

EXHIBIT C



RICHARD C. PLEUS, PhD, EXPERT REPORT:

**CRITIQUE OF THE
FINAL BASELINE HUMAN HEALTH RISK ASSESSMENT FOR THE ANACONDA
SMELTER NPL SITE, ANACONDA, MONTANA (CDM, 1996) AND
REASSESSMENT OF SOIL SCREENING LEVELS
FOR THE OPPORTUNITY COMMUNITY**

Regarding

Montana Second Judicial District Court, Silver Bow County
Christian et al. v. BP Amoco Corp., et al.,
Cause No. DV-08-173 BN

Signature

A handwritten signature in black ink, appearing to read "R. Pleus", is written over a horizontal line.

April 12, 2013

INTERTOX, INC.
600 Stewart St.
Suite 1101
Seattle, WA 98101

206.443.2115 phone
206.443.2117 facsimile



TABLE OF CONTENTS

EXECUTIVE SUMMARY	iv
1.0 INTRODUCTION.....	1
2.0 SCIENTIFIC REVIEW OF THE BASELINE HUMAN HEALTH RISK ASSESSMENT FOR THE ANACONDA SMELTER NPL SITE.....	2
2.1 Soil Screening Level Calculations	2
2.2 Review of Key Exposure Parameters and Risk Assumptions	5
2.2.1 Soil Ingestion Rate (IR).....	5
2.2.2 Fraction Ingested that is Soil (FS) and Dust (FD)	6
2.2.3 Relative Concentration of Arsenic in Dust ($CR_{\text{soil-dust}}$)	7
2.2.4 Oral Bioavailability Factor for Soil and Dust (BAF_{soil} and BAF_{dust}).....	8
2.2.5 Exposure Duration (ED_a and ED_c).....	23
2.2.6 Toxicity Criteria	23
2.3 Exposure Pathways Not Considered	23
3.0 RECALCULATION OF SITE-RELATED RISKS AND SOIL SCREENING LEVELS	25
3.1 Quantification of Exposure	25
3.1.1 Estimation of Exposure Point Concentrations.....	26
3.1.2 Additional Complete Exposure Pathways	27
3.1.3 Revised Exposure Assumptions for Soil and Dust Ingestion Pathways.....	39
3.2 Recalculation of Site-Related Risks	40
3.3 Recalculation of the Soil Screening Level	42
4.0 COMPARISON TO CLEANUP LEVELS AT OTHER SITES	43
5.0 IMPACT OF ALTERNATIVE EXPOSURE ASSUMPTIONS	53
5.1 Relative Oral Bioavailability (RBA) Factors	53
5.2 Relative Concentration of Arsenic in Dust.....	54
5.3 Soil + Dust Ingestion Rates	54
5.4 Produce Consumption Rates	55
5.5 Meat Consumption Rates	56
6.0 SUMMARY AND CONCLUSIONS	56
7.0 REFERENCES	58



LIST OF APPENDICES

APPENDIX A. Curriculum Vitae of Richard C. Pleus

LIST OF TABLES

TABLE 1. ACTION LEVELS FOR ARSENIC IN SURFACE SOIL AND WASTE IN THE ARWW&S OU (U.S. EPA, 1998A).....	1
TABLE 2. RISK-BASED SCREENING LEVELS FOR ARSENIC IN SOIL CALCULATED FOR THE RESIDENTIAL EXPOSURE SCENARIO IN THE ANACONDA SMELTER NPL SITE BASELINE HHRA (CDM, 1996) ...	3
TABLE 3. EXPOSURE PARAMETERS USED TO CALCULATE ARSENIC SOIL SCREENING LEVELS FOR THE RESIDENTIAL SCENARIO IN THE ANACONDA SMELTER BASELINE HHRA (CDM, 1996)	4
TABLE 4. SUMMARY OF RELATIVE ORAL BIOAVAILABILITY ESTIMATES FOR ARSENIC IN SOIL IMPACTED BY MINING OR SMELTING ACTIVITIES	18
TABLE 5. SUMMARY OF SOIL AND GROUNDWATER SAMPLING DATA FOR ARSENIC COLLECTED IN THE OPPORTUNITY COMMUNITY IN JUNE 2012.....	26
TABLE 6. EXPOSURE POINT CONCENTRATIONS (EPCs) USED IN THE REVISED HHRA FOR THE OPPORTUNITY, MONTANA COMMUNITY	27
TABLE 7. EXPOSURE PARAMETERS USED IN THE RISK CALCULATIONS FOR THE RESIDENTIAL SCENARIO AT THE OPPORTUNITY, MT SITE.....	29
TABLE 8. SUMMARY OF PATHWAY-SPECIFIC LIFETIME EXCESS CANCER RISKS FOR OPPORTUNITY COMMUNITY RESIDENTS, RME SCENARIO	41
TABLE 9. SOIL CLEANUP LEVELS FOR ARSENIC IN SOIL FOR RESIDENTIAL/ UNRESTRICTED USE FOR U.S. STATES ^A	43
TABLE 10. ACTION LEVELS FOR ARSENIC IN SOIL AT SELECTED U.S. SITES	45



EXECUTIVE SUMMARY

I have been asked by attorneys (Beck & Amsden, PLLC, of Bozeman, MT) representing a group of citizens in Opportunity, MT to assess the U.S. EPA risk assessment used to derive soil action levels for arsenic, with particular focus on the residential clean-up action level of 250 parts per million (ppm, equivalent to milligrams/kilogram or mg/kg) soil. Arsenic and other chemicals were deposited on the land from the operation of a local smelter. The particular point in question is whether the clean-up level for arsenic in residential soil was developed in a manner consistent with U.S. EPA risk assessment practices.

Montana's Anaconda Regional Water, Waste, and Soils (ARWW&S) Operable Unit (OU) covers approximately 300 square miles in the southern Deer Lodge Valley and its surrounding foothills, and includes the Opportunity Ponds, North Opportunity, South Opportunity, Old Works/ Stucky Ridge, and Smelter Hill subareas. The North Opportunity and South Opportunity subareas in particular include a mixture of rural/residential, agricultural, and open space/ recreational uses. The U.S. EPA Superfund Record of Decision (ROD) for the Anaconda Company Smelter in Anaconda, MT set action levels for arsenic in soils at the ARWW&S OU that vary according to land-use designation. The action levels range from 250 ppm (residential) to 2,500 ppm (open space).

The ROD action levels were selected in part according to the risk-based screening levels presented in the *Final Baseline Human Health Risk Assessment, Anaconda Smelter NPL Site, Anaconda, MT*, (Baseline HHRA) prepared by CDM (1996) for U.S. EPA, which calculated human health risk-based screening levels for various receptors, including residents. As such, I conducted a review of the Baseline HHRA. I note in this report a number of problems with the Baseline HHRA, including omissions of exposure pathways and incorrect calculation of the bioavailability factor. Other concerns include the experimental design of the monkey study used to determine the bioavailability factor.

A site-specific risk assessment for arsenic was performed that included relevant and defensible exposure pathways and corrected mistakes in the Baseline HHRA where applicable. The risk assessment was conducted in a manner consistent with standard U.S. EPA guidance, and incorporates site-specific exposure information, including the concentration of arsenic in dust relative to soil and information from community residents that indicates they consume, or have consumed, homegrown produce, and in some cases have raised livestock for consumption.

This risk assessment yields an estimated arsenic cancer risk of 2.5×10^{-4} , which is 4.5-fold higher than the risk of 5.51×10^{-5} estimated for the Opportunity resident Reasonable Maximum Exposure (RME) scenario in the Baseline HHRA. If the ROD action level of 250 ppm is used with the equations and assumptions applied in this assessment, the estimated lifetime excess cancer risk for an Opportunity resident would be 3.6×10^{-4} , which is 4.3-fold higher than the risk of 8.4×10^{-5} that the Baseline HHRA and the ROD assumes is associated with this action level. These risks are greater than U.S. EPA's general acceptable risk threshold of 1×10^{-4} . These risk estimates are solely arsenic based; other chemical exposures, not included here, would increase the risk estimate.

The soil screening level calculated in the current report, based on an acceptable lifetime excess cancer risk level of 1×10^{-5} , is approximately 8 ppm, compared to the ROD action level of 250 ppm. This screening level is appropriate and consistent with other arsenic soil action levels established nationwide. The U.S. EPA ROD action level of 250 ppm is one of the highest levels for arsenic in the U.S. EPA RODs nationwide.



Regarding our risk calculations, where we could not obtain better scientific data, we used the same parameters as the Baseline HHRA conducted in 1996. For example, while I believe for several reasons that the site-specific monkey study underestimates bioavailability, we used values from that study in this assessment. If the bioavailability was in fact higher than indicated by the monkey study, the risk estimated here would be greater than 2.5×10^{-4} ; as such, my assessment is conservative and if an alternative estimate of relative bioavailability were used, the estimated risks would be calculated to be higher.

My review of the U.S. EPA Superfund ROD for the Anaconda Company Smelter in Anaconda, MT (U.S. EPA, 1998a), the *Final Baseline Human Health Risk Assessment, Anaconda Smelter NPL Site, Anaconda, MT* (CDM, 1996) has found that their arsenic risk estimate and residential action level of 250 ppm is not appropriate. According to the standard practice of toxicological risk assessment, the documents' calculations contain a number of errors and omissions. I further note that, when using a standard risk assessment approach, the 250 ppm figure presents a greater estimate of cancer risk than the documents indicate. Using current data and practices, I have found a scientifically reliable soil screening level to be approximately 8 ppm. This is assessed on a more probable than not basis.



1.0 INTRODUCTION

I have been asked by attorneys (Beck & Amsden, PLLC, of Bozeman, MT) representing a group of citizens in Opportunity, MT to assess the U.S. EPA risk assessment that was the basis for soil action levels for arsenic at the Anaconda Regional Water, Waste, and Soils (ARWW&S) Operable Unit (OU) of the Anaconda Company Smelter National Priority List (NPL) site, with particular focus on the residential soil action level of 250 parts per million (ppm, equivalent to milligrams arsenic /kilogram soil or mg arsenic/kg soil). Arsenic and other chemicals were deposited on the land from the operation of the smelter. I have been asked whether the action level for residential soil was developed in a manner that reflects valid methodologies for predicting exposure and risk, and whether the action levels are appropriately health protective according to U.S. EPA risk assessment practices. I reviewed in more detail the assumptions and results of the Baseline HHRA for the Anaconda Smelter NPL Site and the soil screening levels. I was assisted by scientists in my office, who I directed to conduct specific tasks, including research and calculations. In conducting the evaluation, we relied upon current risk assessment practices, knowledge of arsenic behavior, fate, and toxicity, site-specific information, and comparison to other sites. I base the opinion stated on my education, training, and experience, research I have conducted on similar smelters, and research I have performed specific to this project.

Montana's Anaconda Regional Water, Waste, and Soils (ARWW&S) Operable Unit (OU) covers approximately 300 square miles in the southern Deer Lodge Valley and its surrounding foothills, and includes the Opportunity Ponds, North Opportunity, South Opportunity, Old Works/ Stucky Ridge, and Smelter Hill subareas. The North Opportunity and South Opportunity subareas in particular include a mixture of rural/residential, agricultural, and open space/ recreational uses. The U.S. EPA Superfund Record of Decision (ROD) for the Anaconda Company Smelter in Anaconda, MT (U.S. EPA, 1998a) set action levels for arsenic in soils at the ARWW&S OU according to land-use designation. Table 1 summarizes the action levels for arsenic in surface soil and waste reported in the ROD; the action levels range from 250 to 2,500 ppm. The lowest level action levels are for residential soil and the highest are for steep slopes and open spaces.

Table 1. Action Levels for Arsenic in Surface Soil and Waste in the ARWW&S OU (U.S. EPA, 1998a)

Land Use Designation	Media	Concentration (ppm)	Risk
Residential	Soil and Waste	250	8×10^{-5}
Commercial/Industrial	Soil and Waste	500	4×10^{-5}
Recreational	Soil and Waste	1,000	4×10^{-5}
Agricultural	Soil only	1,000	1×10^{-4}
Steep Slope/ Open Space	Soil only	2,500	1×10^{-3}

Per the ROD, these action levels were selected in part based on the risk-based screening levels presented in the *Final Baseline Human Health Risk Assessment, Anaconda Smelter NPL Site, Anaconda, MT*, prepared by CDM (1996) for the U.S. EPA, which calculated human health risk-based screening levels for residents, commercial/ industrial workers, agricultural workers, and dirt



bike riders exposed to soils within the Community Soils OU located within the ARWW&S OU geographic area. As described in the ROD (p. 28):

Because the Community Soils OU is located within the ARWW&S OU geographic area and shares one of the primary sources of contamination (i.e., soils contaminated by deposition of historical aerial emissions from the smelter), the risk-based screening levels presented in the Anaconda Smelter Site HHRA [Human Health Risk Assessment] are applicable to soils of the ARWW&S OU contaminated by historical smelter emissions.

The ROD describes the source of contamination to the local soils as follows (p. 28):

The two primary sources of contamination within the ARWW&S OU are soils impacted by historic air emissions from the Old Works and Anaconda Smelter stacks, and tailings and other wastes remaining from the smelting processes. Historical smelting activities resulted in widespread, aerial deposition of fugitive dusts and contaminants released from stacks, resulting in contamination of soils in the ARWW&S OU. Materials released from the smelter stacks were small particulates not captured by emission controls in place...

The ROD further states (p. 29):

...The primary release mechanism for tailings and slag is wind erosion, although release to ground water via infiltration/percolation and to soils and surface water via runoff also occurs. Contamination in air emissions is transported via dry or wet deposition from the air into three secondary sources: soil, surface water, and sediment. Transport of contaminants also occurs among secondary sources.

Regarding the level of cancer risk that the Agency deemed acceptable, the ROD (p. 31-32) reports that "EPA has developed action levels for surface soil and wastes for the targeted cancer risk range of $1E-04$ to $1E-06$." Regarding specific action levels, the criteria they used to select the levels are not defined, described as "based on technical and risk management considerations."

The results, briefly found that the Baseline HHRA contains errors or considerations not accounted for and/or assumptions that have not been updated according to scientific and site-related knowledge. Based on these findings, and our knowledge of the site, I evaluated potential human health risks to residents of the Opportunity, MT community associated with arsenic concentrations in soil, dust, and other media, and recalculated residential soil screening levels. We compared these screening levels to action levels established by U.S. EPA at other sites, and found that the action levels set in the ROD are high relative to these sites.

2.0 SCIENTIFIC REVIEW OF THE BASELINE HUMAN HEALTH RISK ASSESSMENT FOR THE ANACONDA SMELTER NPL SITE

In Sections 2.1, 2.2, and 2.3, we describe and comment on the assumptions used to calculate these screening levels.

2.1 Soil Screening Level Calculations

The action level established for arsenic in residential soils within the ARWW&S OU is based on the risk-based soil screening levels calculated in the Baseline HHRA (CDM, 1996). U.S. EPA currently describes arsenic as a Group A human carcinogen (IRIS, 2013); it was classified the same in 1996. The expression of risk for cancer causing agents is a risk level of "N" in a million (" $N \times 10^{-6}$ "),



which implies a likelihood that up to “N” people, out of one million equally exposed, would develop cancer if exposed to the given concentration at the assumed exposure level over 70 years (an assumed lifetime). This risk estimate is an upper bound excess cancer risk that is in addition to any cancer risk borne by the person if they were not exposed to this agent. A risk of 1×10^{-5} is equal to 1 in 100,000 and 1×10^{-4} is equal to 1 in 10,000.

The Baseline HHRA calculates a range of “risk-based screening levels” for arsenic in soil for the reasonable maximum exposure (RME) scenario (which represents “an exposure well above the average but still within the range of those possible;” CDM, 1996) and central tendency exposure (CTE) scenario (which “uses exposure assumptions that predict an average or best estimate exposure to an individual;” CDM, 1996), assuming residential exposure. Per U.S. EPA’s *Superfund Standard Default Exposure Factors for the Central Tendency and Reasonable Maximum Exposure* (U.S. EPA, 1993a), which is cited by CDM (1996) as the source of default exposure parameter assumptions used in the Baseline HHRA, the RME “can be equated to about the 90th percentile of the population distribution,” and is defined as “the highest exposure that is reasonably expected to occur at a site and in practice is estimated by combining upper bound (90-95th percentile) values for some but not all exposure parameters.”

Arsenic soil screening levels calculated in the Baseline HHRA using different acceptable lifetime excess cancer risk assumptions for the RME and CTE residential scenarios are shown in Table 2.

Table 2. Risk-Based Screening Levels for Arsenic in Soil Calculated for the Residential Exposure Scenario in the Anaconda Smelter NPL Site Baseline HHRA (CDM, 1996)

Exposure Scenario	Reasonable Maximum Exposure (RME) Scenario	Central Tendency Exposure (CTE) Scenario
Excess Cancer Risk	1 in 100,000	1 in 10,000
Screening Level (ppm)	29.7	185.2

1×10^{-5}

29.7

185.2

The action level of 250 ppm for the residential land use designation cited in the ROD equates to a lifetime excess cancer risk of approximately 8.4×10^{-5} for the RME scenario (i.e., 8.4 in 100,000), or nearly 1 in 10,000, based on these assumptions.

The screening levels were derived for the residential scenario based on a resident exposed to arsenic by only two exposure pathways, soil ingestion and ingestion of indoor dust, as follows (CDM, 1996):

$$SL_{soil} \text{ (mg/kg, or ppm)} = \frac{TR \times AT}{CF \times EF \times SF_o \times \left(\frac{IRc \times EDc}{BWc} + \frac{IRa \times EDa}{BWA} \right) \times \left[(FS \times BAF_{soil}) + (CR_{soil-dust} \times FD \times BAF_{dust}) \right]}$$

Where:

SL_{soil}	=	Screening level for soil (mg/kg soil, or ppm)
TR	=	Target cancer risk (unitless)
AT	=	Averaging time (d)
CF	=	Conversion factor (0.001 kg/mg)
EF	=	Exposure frequency (d/yr)
SF_o	=	Oral cancer slope factor (mg/kg-d) ⁻¹



IR_c	=	Soil ingestion rate by a child (mg/d)
ED_c	=	Exposure duration for a child (yr)
BW_c	=	Body weight for a child (kg)
IR_a	=	Soil ingestion rate by an adult (mg/d)
ED_a	=	Exposure duration for an adult (yr)
BW_a	=	Body weight for an adult (kg)
FS	=	Fraction ingested that is soil (unitless)
BAF_{soil}	=	Oral bioavailability of arsenic in soil (unitless)
$CR_{soil-dust}$	=	Relative concentration of arsenic in dust (unitless)
FD	=	Fraction ingested that is dust (unitless)
BAF_{dust}	=	Oral bioavailability of arsenic in dust (unitless)

Numerical values for the parameters used to calculate the soil screening levels are shown in Table 3.

Table 3. Exposure Parameters Used to Calculate Arsenic Soil Screening Levels for the Residential Scenario in the Anaconda Smelter Baseline HHRA (CDM, 1996)

	350 d/yr	350 d/yr
EF		
EF	350 (d/yr)	350 (d/yr)
IR_c	200 mg/d	100 mg/d
ED_c	6 yr	2 yr
BW_c	15 kg	15 kg
IR_a	100 mg/d	50 mg/d
ED_a	24 yr	7 yr
BW_a	70 kg	70 kg
FS	45%	45%
BAF_{soil}	18.3%	18.3%
$CR_{soil-dust}$	43%	43%
FD	55%	55%
BAF_{dust}	25.8%	25.8%

Per U.S. EPA (1993a), for the RME scenario, exposure assumptions corresponding to the 90 to 95th percentile of values for a given assumption were targeted as default factors for intake/contact rate, exposure frequency, and exposure duration. For body weight and exposure concentration, average values were targeted.



In addition, the Baseline HHRA calculates “total arsenic cancer risk” for a number of subareas of the site, including Opportunity, based on assumed exposure to arsenic through ingestion of soil and dust and the above exposure assumptions. For Opportunity, the estimated cancer risk is 5.5×10^{-5} for the residential RME scenario and 7×10^{-6} for the residential CTE scenario. These estimates were based on assumed 95th percentile upper confidence limit (UCL) of the mean soil and dust concentrations in Opportunity of 145.1 ppm and 100.8 mg/kg dust, respectively.

2.2 Review of Key Exposure Parameters and Risk Assumptions

2.2.1 Soil Ingestion Rate (IR)

The soil ingestion rate parameter describes how much soil (or dust) a person (adult or child) consumes on a daily basis. Soil ingestion typically occurs incidentally, as a result, for example, of “hand-to-mouth” behaviors. CDM (1996) assumed the following soil ingestion rates (to reflect the combined rate of consumption of soil and dust):

- RME adult: 100 mg soil/d
- RME child: 200 mg soil/d
- CTE adult: 50 mg soil/d
- CTE child: 100 mg soil/d

These are U.S. EPA default assumptions for the RME and CTE scenarios (U.S. EPA, 1993a), and are widely cited and used by the U.S. EPA (the Agency) and state agencies in Baseline HHRA for these scenarios. In general, these are consensus values based on a compendium of data from many studies that focus largely on children. While U.S. EPA (1993a) states that the adult RME value of 100 mg soil/d is based on a study by Sedman (1989), the Sedman (1989) paper indicates that it lacks scientific support for the value for consumption of soil and dust. The author states:

No information could be identified that provides a sound technical basis for estimating the quantity of soil ingested by older children and adults. While other investigators have assumed that adults ingest a significant quantity of soil and employ an assumed rate of soil ingestion for adults, no basis for these assumptions could be identified...Investigators who have advanced exposure scenarios that include soil ingestion for adults assume that adults ingest less soil than children.

Sedman develops other soil ingestion rates for a range of increasing ages via extrapolation. These values are based on measured and estimated soil ingestion rates for toddlers (they report that for children from 1 to 3 years old, daily soil ingestion is 590 mg soil/d) combined with data about increases in blood lead levels at increasing ages and assumptions about changes in mouthing behaviors. For children ages 2 to 9, the cited soil ingestion rates range from 590 mg soil/d to 300 mg soil/d, and for adults (age 18-70) the cited rate is 100 mg soil/d.

The child RME value of 200 mg soil/d reportedly reflects the consensus opinion of a U.S. EPA workgroup and is “believed to correspond to a conservative estimate of an average ingestion rate for this age group over a chronic period of exposure” (U.S. EPA, 1993a). However, per U.S. EPA “the available data did not support identification of the 90 or 95 percentile value. It was the consensus among workgroup participants that over the 6 year period of concern for this receptor category, the value of 200 mg soil/day was reasonable to assume.”



While CDM (1996) describes a week-long study to measure soil and dust ingestion in 64 people living in Anaconda that was performed by Dr. Edward Calabrese, the results of this study were only used as scientific support for the default values. CDM states (p. 3-37):

Using a single 'best tracer' methodology, the soil and dust ingestion rate median was 51 mg/d, the mean was 117 mg/d, and the 90th percentile was 277 mg/d. The 'four best tracers' study resulted in an ingestion rate median of 39 mg/d, a mean of 83 mg/d and a 90th percentile of 273 mg/d. The findings in the Anaconda soil and dust ingestion study support the Superfund Program's usual approach of assuming ingestion of 100 mg soil and dust per day as a CTE assumption and 200 mg soil and dust per day as a RME assumption for soil and dust ingestion rates (IRs) of children age 0-6 years. Though default assumptions are used for soil and dust IRs for children, these assumptions are clearly consistent with the available site-specific data.

Overall, these estimated soil ingestion rates are assumed to represent average incidental soil ingestion rates by children. It is further assumed that the potential for incidental ingestion of soil is greater in young children than older children and adults because of the increased hand-to-mouth behaviors at younger ages.

These assumptions do not consider pica behaviors (i.e., the recurrent intentional ingestion of unusually high amounts of soil, typically by children, on the order of 1,000-5,000 mg soil/day or more; U.S. EPA, 2008), which would dramatically increase the dose for a child that engages in these behaviors.

A very large number of additional studies have been conducted to attempt to measure soil and dust ingestion by children, most using "tracer" methods. These have been reviewed by U.S. EPA (2008) and other regulatory agencies (e.g., CA OEHHA, 2002). Because of the uncertainties in the results of soil ingestion studies, these agencies continue to recommend use of the default values for the soil ingestion parameter. As such, use of the default soil ingestion assumptions of 100 mg soil/d for adults and 200 mg soil/d for children in the Baseline HHRA appear reasonable.

2.2.2 Fraction Ingested that is Soil (FS) and Dust (FD)

CDM (1996) assumed that 45% of the total soil and dust consumed in a day is soil and 55% is dust. Regarding these assumptions, CDM (1996) states (p. 3-38),

It was assumed for both adults and children that of the total soil and dust ingested, 55% derives from indoor dust and 45% from soil. An assumption for fractionating dose between soil and dust is necessary since (1) indoor dust and soil arsenic and lead concentrations are not the same at exposure points, (2) different bioavailability estimates are used for dust and soil for arsenic, and (3) many studies have found a significant contribution of indoor dust to exposure.

While U.S. EPA is not specific about its rationale for selecting these values, these are typical U.S. EPA default values applied for the soil/dust ingestion pathways: in their *Exposure Factors Handbook*, U.S. EPA (2011b) recommends assuming that the relative proportions of soil and dust ingested by children are 45% soil and 55% dust, and this assumption is also used in U.S. EPA's Integrated Exposure and Uptake Biokinetic (IEUBK) model for lead in children (U.S. EPA, 1994a).

In the absence of other data, use of 45%/55% soil/dust for the relative fraction ingested assumption appears reasonable for evaluating exposure to arsenic in soil and dust.



2.2.3 *Relative Concentration of Arsenic in Dust ($CR_{\text{soil-dust}}$)*

CDM (1996) assumed that the concentration of arsenic in dust was 43% of the concentration of arsenic in soil. CDM (1996) bases this estimate on measurements of arsenic concentrations in soil and dust in Anaconda and Opportunity reported by Bornschein (1992 and 1994). As described by CDM (1996), soil samples were collected from several locations within each yard, and in general, three interior dust samples were collected from each home, with samples “intended to represent areas frequented by children, and included a floor area directly inside the main entry to the home, a floor area in the most frequently occupied room (usually living room or kitchen) and a floor area in the child’s bedroom” (p. 2-11). Regarding the relative concentrations in soil and dust, CDM states that (p. 3-24) “...analysis of paired soil and interior dust measurements for arsenic suggest a transfer coefficient of 0.43 for movement from soil to dust (Bornschein 1994).”

The basis for this original assumption was not verified. However, a more recent study of arsenic concentrations in soil and dust was conducted in the Community Soils OU, including Opportunity, in 2006 and 2007 (Pioneer Technical Services, 2009). Samples of exterior soil and interior dust (from the main living space and the attic) were collected from 10 homes in Opportunity, as well as 17 homes in Anaconda West and 15 homes in Anaconda East. The results showed the following:

- In Opportunity (sample size (n) = 10), the average relative concentration of arsenic in main indoor living area dust vs outdoor soil was 170% (range 60% to 490%), with median and 75th percentile values of 110% and 200%, respectively. In other words, on average, the concentration of arsenic in indoor living area dust was nearly twice that in outdoor soil, for samples collected at the same residence.

When concentrations in attic dust were compared to those in dust from the main indoor living area of the same home, attic concentrations were higher in six of 10 cases (the average relative concentration of arsenic in dust from the attic vs. the main indoor living area was 240%, range 10% to 730%, with median and 75th percentile values of 120% and 350%, respectively). In other words, on average, the concentration of arsenic in attic dust was more than twice that in dust from the indoor living area, for samples collected at the same residence.

- Combining all data collected outside of Opportunity in Anaconda West and Anaconda East (n = 32), the average relative concentration of arsenic in main indoor living area dust vs outdoor soil was 110% (range 30% to 310%), with median and 75th percentile values of 90% and 140%, respectively. Thus, the tendency for higher concentrations in indoor dust vs. outdoor soil was consistent in Anaconda as well as Opportunity.

Attic dust concentrations tended to be higher than main indoor living area dust concentrations at these locations as well: attic concentrations were higher in all but three of the cases, with concentrations sometimes dramatically higher in the attics (the average relative concentration of arsenic in dust from the attic vs. the main indoor living area was 1,160%, range 7% to 2,970%;. Median and 75th percentile relative values were 870% and 1,880%, respectively).

- Combining all data for Opportunity, Anaconda West, and Anaconda East (n = 42) to increase statistical robustness, the average relative concentration of arsenic in main indoor living area dust vs outdoor soil was 130% (range 30% to 490%), with median and 75th percentile values of 100% and 150%, respectively.

The average relative concentration of arsenic in dust from the attic vs. the main indoor living area was 940% (range 7% to 2970%), with median and 75th percentile values of 720% and 1,610%, respectively.



These data indicate that the ratio of concentrations in indoor dust in the main area versus concentrations in outdoor soil in Opportunity and Anaconda homes are comparable, and that the relative concentration in indoor dust to outdoor soil is much higher than that assumed in the CDM (1996) Baseline HHRA. In addition, at most of the sampled locations, the attic dust concentration was much higher than the concentration in dust in the main living area.

Whereas the CDM (1996) assessment assumed that the indoor dust concentration was 43% of the outdoor soil concentration, more recent data, including data specific to the Opportunity community, indicate that the concentration of arsenic in indoor dust should be assumed to be higher than in outdoor soil.

2.2.4 Oral Bioavailability Factor for Soil and Dust (BAF_{soil} and BAF_{dust})

CDM (1996) assumed that 18.3% of arsenic in ingested soil and 25.8% of arsenic in ingested dust is bioavailable. Oral bioavailability factors are critical for evaluation of soil ingestion pathways, as the assumed value directly affects estimated dose and thereby risk. The bioavailability estimates assumed in CDM (1996) are based on a site-specific study (cited as Battelle 1994¹) in which cynomolgus monkeys were administered either soluble arsenic or arsenic in soil or dust collected in the Anaconda community. Arsenic was then measured in urine, feces, and blood.

Appendix C of CDM (1996) (*Review of the Battelle Columbus Report: Determination of the Bioavailability of Soluble Arsenic and Arsenic in Soil and Dust Impacted by Smelter Activities following Oral Administration in Cynomolgus Monkeys, Memorandum from Christopher Weis to Charlie Coleman and Susan Griffin, November 10, 1994*) and Freeman et al. (1995) describe the monkey study and its results. As described, arsenic was administered to monkeys as a single dose in one of the following ways:

- Intravenous (IV) dosing of a soluble arsenic solution (as sodium arsenate)
- Oral gavage dosing of a soluble arsenic solution (as sodium arsenate)
- Oral ingestion dosing, in capsules, of a test soil containing arsenic
- Oral ingestion dosing, in capsules, of a test dust containing arsenic

The test soil was a composite of samples collected in the Anaconda community from the surface (0-2") horizon of six play areas or bare area soils. The test house dust was collected with a vacuum from carpets in living areas and children's bedrooms. Samples were dried at 80°C, then sieved to a particle size of <250 µm. The samples were analyzed for arsenic concentration then blended to yield a final concentration of 410 ppm.

The study group consisted of only three animals that were cycled through each of the four treatment groups at different times during the study. Urine, fecal and cage rinse samples were reportedly collected prior to dosing and, after dosing, once every 24 hours for 7 days. Excretion of arsenic to urine and feces was reportedly essentially complete after 72 hours.

Since we did not have access to all of the study details (e.g., animal handling, dose administration, and other variables that can significantly influence experimental outcomes), we cannot comment on the validity of all of the experimental methods. However, some available data cause concern and

¹ We were unable to locate the original study (cited as: Battelle. 1994. Determination of the Bioavailability of Soluble Arsenic and Arsenic in Soil and Dust Impacted by the Smelter Activities Following Oral Administration in cynomolgus Monkeys. Amended Final Report. March). However, Appendix C of CDM (1996) reviews the study, and Freeman et al. (1995) presents the study methodology and results (although the calculated bioavailability levels presented in Freeman et al. (1995) differ somewhat from those applied in CDM (1996)).



suggest significant uncertainty about arsenic dosing and recovery methods. For example, the rate of recovery of urinary and fecal arsenic from the IV dosing groups was consistently lower than from the other groups; per Freeman et al. (1995), the total percentage recovery of arsenic from the IV group was 79.7%, compared to 94.4%, 101%, and 95.4% for the gavage sodium arsenate, oral soil, and oral dust groups, respectively. The reasons for this difference were not determined but, per the Appendix C review:

It is likely that the IV dose remained bound to tissue components, cellular blood components or plasma proteins making it more inaccessible to glomerular filtration or biliary excretion than the oral doses.

As applied in the Baseline HHRA, absolute percent bioavailability of arsenic via each of the routes was estimated by determining the “area under the curve” (AUC) based on the urinary arsenic measurements. In addition, for application to the Baseline HHRA, the urinary recovery results were “normalized” to compensate for the poor recovery from the IV group by dividing the absolute bioavailability reported for the ingestion route by the absolute bioavailability for the IV route for the same animal. CDM (1996) reported the following mean adjusted absolute bioavailability estimates from urine concentrations based on these calculations:

- Gavage: 90.9%
- Soil: 18.3%
- Dust: 25.8%

These bioavailability estimates were applied in the cleanup level calculations².

However, as described below, we note that the bioavailability estimates were calculated erroneously, which resulted in lower levels. In addition, some of the study design variables created in an experimental exposure scenario that differed vastly from what might occur in a residential exposure situation. Furthermore, the bioavailability factors used in this study are low when compared to other values in the literature, in some cases by two- to three-fold. Together, these factors raise concern about the scientific validity of this study and suggest that these bioavailability estimates underestimate site-related risks.

2.2.4.1 CDM (1996) Incorrectly Applies Absolute Rather than Relative Bioavailability Factors

Per U.S. EPA (2007a), the term “bioavailability” as applied to the evaluation of chemical exposure refers to, “The fraction of an ingested dose that crosses the gastrointestinal epithelium and becomes available for distribution to internal target tissues and organs.”

However, when applying a bioavailability factor in risk assessment calculations, a distinction must be made between “absolute” and “relative” bioavailability. Absolute bioavailability describes that total fraction of the dose that is absorbed and available, whereas relative bioavailability compares the bioavailability of the compound in the exposure medium of interest (e.g., soil) to that in the medium upon which the toxicity criterion is based.

² Freeman et al. (1995) also attempt to correct the results of urinary recovery for the oral routes to compensate for the poor recovery from the IV group. However, in their calculations, they apply the “correction factor” twice in a manner that it cancels itself out and the net result is no correction factor is applied. Consequently, the adjusted relative bioavailability estimates reported in Freeman et al. (1995) (19.2% for dust and 13.8% for soil) differ from those reported and applied in CDM (1996).



With regard to arsenic, the application of relative bioavailability estimates is described by Roberts et al. (2007) in a review of oral bioavailability factors for arsenic:

The default assumption used in risk assessments is that the extent of gastrointestinal absorption of arsenic from soil is equivalent to its absorption under the conditions in which the toxicity value was derived (NRC, 2003), which in the case of arsenic is from water. Absorption from water is the relevant comparison for arsenic because the cancer slope factor used to estimate excess cancer risks was developed from studies of individuals exposed to arsenic in drinking water.

Thus, for arsenic, the relative oral bioavailability (RBA) based on urinary excretion data should be calculated as follows (U.S. EPA, 2010):

$$RBA \text{ of test material} = \frac{\text{Urinary excretion fraction of arsenic in test material (soil or water)}}{\text{Urinary excretion fraction of sodium arsenate in water}}$$

Since the oral bioavailability estimates applied in CDM (1996) reflect the percent of the total delivered dose in soil that is excreted, and are not normalized relative to the excreted dose following ingestion of arsenic in water, they are absolute, not relative, bioavailability factors.

Applying the Freeman et al. (1995) data on urinary excretion of arsenic following ingestion of soil or dust and following gavage administration of sodium arsenate in water to this equation yields relative bioavailability estimates of $20.3 \pm 3.4\%$ for soil and $29.1 \pm 0.7\%$ for dust. Thus, the RBA values for soil and dust are 2.0 and 3.3 percentage points higher, respectively, than the bioavailability factors assumed in the Baseline HHRA. Use of the RBA values results in higher assumed doses and, therefore, higher assumed risks at a given soil or dust concentration.

In another study of the oral bioavailability of arsenic in primates, Roberts et al. (2007) reported that the average percentage of arsenic recovered in urine after oral (gavage) administration of sodium arsenate in water ($40.6\% \pm 10.1\%$) was substantially lower than after IV administration of sodium arsenate ($80.5\% \pm 10.2\%$), "indicating incomplete oral absorption of arsenic from the oral dose in water." Thus, even highly soluble sodium arsenate in water may not be completely absorbed in a given experimental system, and it is essential to determine the relative absorption of arsenic following oral administration in soil (or dust) compared to oral administration in water within the system of interest, rather than simply assume that absorption of arsenic in water would be complete (which is essentially what is assumed if the urinary excretion fraction in soil is not determined relative to water).

The importance of making the "relative" adjustment when using urinary excretion as a surrogate for absorbed arsenic is further illustrated by the potential fate of some of the absorbed arsenic. A fraction of administered arsenic that is absorbed may be eliminated in bile in the feces, or it may enter tissue compartments and thus not be reflected in the recovered urine. U.S. EPA (2010) notes,

If 100% of all absorbed arsenic were excreted in the urine, the UEF [urinary excretion fraction] would be equal to the oral absorption fraction or ABA. However, some absorbed arsenic is excreted in the feces via the bile and some absorbed arsenic enters tissue compartments (e.g., skin, hair) from which it is cleared very slowly or not at all. Thus, the urinary excretion fraction should not be equated with the absolute absorption fraction.

However,

The RBA [relative bioavailability] of two orally administered materials (e.g., a test soil and sodium arsenate) can be calculated from the ratio of the urinary excretion fraction of the two



materials. This calculation is independent of the extent of tissue binding or biliary excretion, because the fraction of absorbed arsenic that is excreted in urine (K_u), which does depend on tissue binding and biliary excretion, cancels in the calculation.

Thus the relative efficiency of recovery of arsenic in the experimental environment (i.e., in urine) is implicitly accounted for by applying relative, as opposed to absolute, bioavailability factors in a risk assessment.

2.2.4.2 Methodological Factors in the Monkey Study, Are More Likely (Than Not) to Have Under-Predicted Absorption

As noted above, it is critical to review the experimental design of a study. The original bioavailability study report was not available; however, the documentation we reviewed indicated that large (bolus) doses of the test material were given to the monkeys during a single dosing period. This experimental protocol is more likely than not to contribute to less efficient absorption compared to if smaller doses are delivered over a period of time, which is more representative of exposure to soil and discussed further below.

In the monkey study, the soil or dust dose was delivered to each monkey during a single dosing period in four capsules, with a 1- to 4-minute interval between each capsule (Freeman et al., 1995). Overall, approximately 3 grams of soil or 3.8 grams of dust were administered to each animal (CDM, 1996). Assuming an average animal body weight of 2.5 kg, this rate of intake (1200 mg soil/kg BW for soil³) is approximately 840-fold higher⁴ than the amount of soil U.S. EPA typically assumes is consumed by an adult under the RME scenario (i.e., 100 mg/70 kg soil-d, or 1.4 mg/kg BW-d) and approximately 90-fold higher⁵ than the amount U.S. EPA typically assumes is consumed by a child under the RME scenario (200 mg/15 kg BW-d, or 13.3 mg/kg BW-d). The review in Appendix C of CDM (1996) notes that "It is plausible that such high doses may have a negative influence on the estimates of arsenic absorption made by the authors;" yet, they do not attempt to characterize its impact on the bioavailability measurement, stating "however, further work is necessary to determine the relationship between arsenic dose and percent absorption."

Other authors have observed that bolus doses can reduce absorption of metals. For example, data on absorption of lead from soils (Mushak, 1998) suggest that bolus administration of a large mass of metal and/or metal-containing soil matrix may be associated with a lesser degree of absorption from the gastrointestinal tract than might result from administration of the same mass in smaller, divided doses. Mushak (1998) references a study by Kierski (1992; a PhD thesis not located) in which soil was administered to rabbits to estimate lead absorption. When soil mass was reduced, relative bioavailability of lead from soil (relative to ingested soluble lead acetate in solution) increased significantly compared to larger soil doses. A number of mechanisms are thought to contribute, including the greater availability of smaller dosing amounts to stomach acids and to chelating and binding effects that may enhance absorption, and the potential that large doses can overwhelm typical biochemical and physiologic mechanisms. Thus, the low bioavailability factors in the Freeman et al. (1995) study, compared to other studies, could be explained by the poor experimental design (as discussed in Section 2.2.4.4, many of the relative bioavailability estimates determined in other studies use an experimental model in which smaller soil doses are administered over a longer period of time).

³ Freeman et al. (1995) estimates that the dose was 1500 mg/kg BW of soil or house dust.

⁴ Appendix C of CDM (1996) states that the dose is 190-fold higher than the typical adult soil ingestion rate.

⁵ Appendix C of CDM (1996) states that the dose is 20-fold higher than the typical child soil ingestion rate.



Steady-state models more closely approximate likely human exposures

In the Freeman et al. (1995) monkey study, arsenic was administered in single doses and arsenic excretion was determined based on collection of urine over 72 hours. U.S. EPA (2012a) identifies several disadvantages of single-dose studies versus steady-state models (in which animals are dosed over several days), including:

- Steady state models more closely mimic the status of the human receptor who receives continuous daily exposure to soil.
- At steady state, urinary excretion of arsenic will be relatively constant over time, and as a result, urinary arsenic excretion rate and urinary excretion fraction can be estimated by averaging multiple estimates obtained from several urine samples collected over time. By contrast, in a single dose study, urinary excretion fraction must be estimated as the cumulative urinary arsenic excretion. This requires absolute accuracy in sampling urine at each interval of the post-dosing observation period.
- Random errors in urine sampling (e.g., reflecting completeness of collection) would be expected to have a larger impact on estimates of the cumulative arsenic excretion in single-dose studies than on average steady-state arsenic excretion in repeat dose studies.

Further, because of the very small number of animals in the monkey study (a total of three animals per group), any biases or errors in the experimental design would have a significant impact on average urinary measurements and result in low bioavailability estimates.

2.2.4.3 The Study of Arsenic in Urine from Anaconda Children Cannot Be Reliably Used to Compare Predicted and Measured Concentrations

CDM (1996) defends the oral bioavailability assumptions applied in the Baseline HHRA in part based on a study in which urine samples were collected from Anaconda children and measured arsenic levels were compared to levels predicted based on the exposure equation and assumptions described above, including the site-specific bioavailability estimates. The urine study is discussed in Appendix D of the Baseline HHRA; the authors suggest that based on their comparison of measured vs. predicted "speciated" (i.e., inorganic) urinary arsenic, the exposure equations and assumptions used in the Baseline HHRA over-predict arsenic uptake from soil (speciated arsenic is assumed to come from soil, dust, and water, where inorganic species predominate, whereas organic arsenic is largely derived from food sources such as fish). However, numerous uncertainties in the methodology limit the ability to draw conclusions based on this urinary arsenic study.

Urine samples were reportedly collected from 373 children in Anaconda. Per Bornschein (1992), urine samples represented the "first catch" of the day. Bornschein (1992) indicates that urine samples were analyzed for total arsenic (inorganic + organic) and/or speciated (inorganic) arsenic, with speciated arsenic representing the sum of As^{+3} , As^{+5} , dimethyl arsenic acid (DMAA) and monomethylarsonic acid (MMAA) (i.e., it does not include organic arsenic such as arsenobetaine, which is a component of total arsenic and is considered to largely come from food, such as seafood). For each child, measured urinary arsenic was compared to levels that were predicted as a function of the estimated absorbed dose of arsenic from various sources and assumed urinary production rates. For speciated arsenic, excretion in g-arsenic/day was predicted as the sum of predicted excretion from ingestion of arsenic in soil, dust, and water, which was in turn was estimated from measured concentrations of arsenic in soil and dust and, where available, water (if residences used community water, a default concentration in water of 0.5 parts per billion (ppb; equivalent to micrograms per liter or $\mu g/L$) was assumed) and assumed intake rates. The same assumptions were used to predict



intake as were used in the HHRA: the bioavailability of arsenic in soil, dust, soil, and water was assumed to be 18.3%, 25.8%, and 100%, respectively, and the soil/dust ingestion rate was assumed to be 200 mg/d for the RME estimate and 200 mg/d for the CTE estimate. This “absorbed” daily dose was assumed to be equivalent to the daily urinary excretion rate. Urinary concentrations were estimated by dividing the estimated daily excretion rate (in g/d) by the assumed daily urine volume (in L/d) per child.

Regarding the environmental media concentration measurements:

- For soil, the 95% upper confidence limit (UCL) concentration of surface soil samples collected in each yard (Bornschein 1992) was used. Bornschein collected composite soil samples to a depth of 2 cm “from several different types of surface conditions within the yard of each home or building, including the perimeter of the home or building, garden areas, play areas, and bare areas of the yard.”
- For dust, composite indoor dust samples were collected, using a small vacuum pump, from three areas within each home or apartment. These areas were intended to represent areas frequented by children, and included floor areas directly inside the main entry to the home, in the most frequently occupied room (usually living room or kitchen), and in the child’s bedroom.
- For water, the authors used a value measured from the primary water faucet, normally the kitchen sink, from a subset of 36 homes that obtained drinking water from local groundwater. Samples consisted of 100 milliliter (mL) taken immediately upon opening the tap. For subjects without a location-specific water sample, the concentration of arsenic in drinking water was assumed to be 0.5 ppb (these samples were assumed to not be contaminated, i.e., not from local groundwater).

The authors compared measured to predicted speciated arsenic in urine (n = 366). Total arsenic excretion (i.e., reflecting inorganic and organic arsenic) was also measured in urine and predicted assuming uptake from food (based on analysis of arsenic in food for a subset of 30 study participants) in addition to uptake from soil, dust, and water. However, CDM (1996) did not consider the total arsenic predictions to be very reliable,

Because of the large standard deviation in the arsenic concentration in food and because of the lack of information on the bioavailability of arsenic in food, there is a large degree of uncertainty associated with predicted total urinary arsenic excretion.

Bornschein states further, “the uncertainty associated with predicted total arsenic excretion is greater than the uncertainty associated with the predicted speciated arsenic excretion.”

Based on review of information provided by CDM (1996) and Bornschein (1992), the following sources of uncertainty in these results are evident:

- *It is unclear how measured concentrations of arsenic in urine reflect longer term average concentrations (and exposures).* The protocol discussed in Bornschein (1992) suggests that repeated urine samples would be collected from subgroups of Anaconda children throughout the year, to capture seasonal variations in concentrations (e.g., exposure to arsenic in airborne dust might be expected to be higher during drier months, and direct contact and ingestion of arsenic in homegrown produce might be expected to be higher during warmer periods). However, CDM (1996) does not indicate when the urine measurements presented in Appendix D were collected. Consequently, it is not known whether measurements reflect “high,” “low,” or “average” exposure periods.
- *“First catch” samples may not reflect within- and between day variations in urine dilution and*



arsenic intake. “First catch” samples reflect measurement of urinary arsenic at a single point in time on the collection day. For chemicals with a short biological half-life (e.g., arsenic), within-individual concentrations in spot urine samples can vary highly between samples, due to within- and between-day variations in urine volume and intake of exogenous compounds (Barr et al., 2005). Factors shown to influence urinary concentrations of these types of chemicals include fasting time, time of day, nature of the last meal, sample dilution, collection method, preservation method, sample interferences, and analytical method (Rasmussen et al., 1999).

- *Urinary excretion volumes were estimated, not measured.* To calculate the predicted concentration of arsenic in urine, the daily excretion rate (in g/d) was multiplied by an assumed urine excretion volume. The assumed excretion volume was based on the child’s age, as follows: for ages 8 to 36 months, 240 mL/d; for ages 36 to 60 months, 355 mL/d; and for ages 60 to 76 months, 432 mL/d. It is unknown how, on an individual basis, estimated and actual excretion volumes varied. Use of a default value could under- or over-estimate urinary concentrations for a given child.
- *It was assumed without verification that all arsenic in water, soil, and dust was “speciated” arsenic (i.e., As^{+3} , As^{+5} , dimethyl arsenic acid (DMAA) and/or monomethylarsonic acid (MMAA)).* Based on the study description and identified protocols for the analysis of arsenic in water, soil, or dust (i.e., Appendix D of the Baseline HHRA and Bornschein 1992), it appears that no special separation procedures were used to speciate arsenic in soil, dust, or water. While, Bornschein (1994) suggests that a small subset of all soil and dust samples were analyzed for speciated arsenic, no details or results are provided. Some of the arsenic measured in soil, dust, or water may have been organic arsenic, which would yield a larger estimated urinary concentration than the measured concentration in urine, which is based only on speciated arsenic.
- *Some absorbed arsenic may accumulate in other tissues and not be excreted in urine; thus, the urinary concentration does not equal the absorbed dose.* As discussed previously, U.S. EPA (2010) notes, “If 100% of all absorbed arsenic were excreted in the urine, the UEF [urinary excretion fraction] would be equal to the oral absorption fraction or ABA. However, some absorbed arsenic is excreted in the feces via the bile and some absorbed arsenic enters tissue compartments (e.g., skin, hair) from which it is cleared very slowly or not at all. Thus, the urinary excretion fraction should not be equated with the absolute absorption fraction.” The urinary excretion concentration could underestimate the actual absorbed dose.
- *The equation used to predict urinary arsenic concentrations does not calculate the absolute absorbed dose, nor does it reflect the same absorbed fraction as the measured concentration in urine.* The measured and predicted urinary concentrations of arsenic reflect two different measures. The bioavailability factor in the risk assessment equation predicts the absorption of arsenic from soil, dust, or other media *relative* to the absorption of the arsenic in the study upon which the toxicity criterion is based—it does not predict the total absorbed dose. In contrast, the measured urinary concentration reflects the fraction of the total absorbed dose that is excreted in urine. Since it is probably that experimental variables in the monkey study impacted the reported RBA values (as discussed in Section 2.2.4.2, above), it does not appear that urinary concentrations can be accurately predicted in children using these values.

Thus, because of one or more deficiencies or gaps in scientific information, it does not appear that it is valid to compare the measured and predicted urinary arsenic concentrations using these methods, or that these comparisons reveal anything about the accuracy of the equations and assumptions used in the Baseline HHRA for estimating doses of arsenic for these scenarios relative to the toxicity criterion dose.



2.2.4.4 Estimates for Other Sites Show Potentially Higher Uptake

Numerous studies have been conducted to measure or estimate the oral bioavailability of arsenic in soil at other sites. In U.S. EPA's (2012a) summary of a total of 103 RBA estimates of arsenic in soil using 88 unique test materials, RBA estimates for arsenic in soil following ingestion ranged from 8 to 61%, including soils from Montana. While the Agency recommends that site-specific data be used where available, in the absence of such data U.S. EPA (2012b) recommended a default value for RBA of arsenic in soil of 60%, based on an upper percentile of the RBAs presented in U.S. EPA (2012a).

Comparison to estimates at other sites provides some insight into the range of possible values and the factors that can impact bioavailability estimates. For example, site- and study-specific factors can influence bioavailability estimates, as follows:

- *The mineral phase of arsenic in soil can impact its bioavailability.* Roberts et al. (2007) suggests that the iron sulfate mineral phase fraction of arsenic (FeAs sulfate) is the best single linear predictor of arsenic RBA, with these two variables being inversely related (i.e., soils with lower iron sulfate fractions have higher bioavailability). For example, Roberts et al. (2007) reports that "Colorado smelter soil" had an iron sulfate fraction of 76.7% and a corresponding RBA of $5 \pm 4\%$ in a cynomolgus monkey study, while a "New York pesticide facility" had an iron sulfate fraction of 0.5% and a RBA in monkeys of $20 \pm 10\%$. However, Freeman et al. (1995) reports the arsenic iron sulfate fraction for the tested Anaconda materials to be 5% for soil and 1% for dust, suggesting that a higher RBA might be expected. Further, while other authors report an inverse association between RBA and the iron oxide fraction (Yang et al., 2005), this relationship isn't necessarily consistent either: for example, Casteel et al. (2003b) reported an iron oxide fraction in two soils from a Butte, Montana Superfund site of 20% and 39%, with reported RBAs (based on studies in immature swine) of 17% and 22% (i.e., the soil with a lower iron oxide fraction had a lower RBA). Thus, clear relationships between mineralogy and RBA estimates are not apparent and it is not evident that soil mineralogy is sufficient to predict RBA given that many other site- and study-specific variables can also affect bioavailability.
- *Arsenic bioavailability may differ in different animal models.* Arsenic bioavailability in soil has been evaluated in rodents, monkeys, and juvenile swine. In attempting to directly compare the results of rodent, monkey, and swine models for the same soils, U.S. EPA (2012a) identifies only one study that evaluated RBA in all three species. This study investigated the RBA of arsenic in soils from four different sources (with arsenic concentrations of 290-388 ppm). For these soils, RBA estimates in swine were highest (range 31-52%), and estimates in monkey and mice were similar (range 25-38% and 21-35%, respectively). However, U.S. EPA indicates that because the sample size was small ($n=4$ soil samples), there is substantial overlap in the uncertainty bounds on the experimental estimates and statistically meaningful comparisons of between-species estimates cannot be made.

In another study, U.S. EPA compares RBA estimates of the same soil materials in swine and mice (U.S. EPA, 2012a). Out of 11 materials, similar RBA estimates were reported for five materials and dissimilar estimates were reported for six. Of the dissimilar estimates, the RBA predicted in mice was less than that predicted in swine in every case. The absolute differences in the RBA estimates (swine – mouse) ranged from $\leq 1\%$ to 28% (average 12%).

When comparing rodents and swine, U.S. EPA (1996a) indicates a preference for the immature swine model to predict bioavailability in humans:

Immature swine were preferred as the test animal for this study because of characteristics



comparable to young children (the age group at greatest risk of ingesting soil or other material containing contaminants). These included similar body size, weight, bone-to-body weight ratio and gastrointestinal anatomy and physiology. In addition, unlike other species such as rats or rabbits, the rate of growth and maturation is slower (a smaller portion of the prepubertal period will occur during the experiment), the cecum (a diverticulum of the large intestine where prolonged exposure to digestive enzymes and fluids occurs) is small, and coprophagia (reingestion of feces) is not required to maintain normal nutritional status. Like humans, swine are monogastric omnivores (stomach and intestinal fluid and bacterial composition are different than herbivores or carnivores), are adaptable to a periodic feeding schedule and have a gall bladder which excretes bile into the small intestine when food is present (some contaminants, such as lead are excreted in bile). Unlike the rat, metabolism and excretion of arsenic in swine is similar to humans. The results of pharmacokinetic studies of lead in immature swine and humans are similar (Weis et al., 1994).

Roberts et al. (2007) derived RBA estimates in monkeys using soil from two sites that had previously been evaluated using a swine model, although the evaluations were not conducted on the same soil samples. In both cases, the monkey RBA estimate was less⁶. Like the Freeman et al. (1995) study, the Roberts et al. (2007) monkey study administered single, very large doses of soil to each study animal (at a soil mass that “did not exceed 1,000 mg/kg[ppm]”, which would be equal to 4,000 to 5,000 mg/d in a single dose for a 4-5 kg monkey). For the reasons discussed in Section 2.2.4.2, administration of these very large bolus soil doses probably resulted in a lower estimate of bioavailability in the monkeys relative to what might occur if smaller doses were administered over time.

U.S. EPA (2012a) summarized results for all three species and concluded the results were generally comparable, but suggests no direct species comparisons are possible at this time. Per U.S. EPA,

Although estimates of RBA of arsenic in soil materials in animal models have not been quantitatively compared to estimates made in humans for the same material, this report shows that RBA estimates obtained from swine, monkey, and mouse for the same test materials are sufficiently similar to suggest that large differences in RBA across mammalian species are unlikely. This increases confidence in extrapolating RBA estimates obtained from these assays to humans.

- *Other study protocol variables can impact measurements.* As discussed in Section 2.2.4.2, a number of experimental parameters within a given study can influence the amount of arsenic that is absorbed, and these variables may differ substantially between studies and from human exposures. Some of these parameters include dose size and the frequency and duration of dosing.

Overall, differences in these variables limit the ability to compare bioavailability estimates across species and across sites. However, in general, U.S. EPA considers the *in vivo* juvenile swine model to be a good model for predicting bioavailability in humans, stating, “available physiological data indicate that young swine are a good model for the human gastrointestinal system” (U.S. EPA, 2010).

⁶ The comparative RBA estimates were as follows: (1) Vasquez Boulevard and I-70 Superfund site (CO; a smelting site) residential soil composite: Monkey = $17 \pm 8\%$ (Roberts et al., 2007); Swine: 31% (mean, range 18-45%) (Casteel et al., 2001); (2) Western U.S. mining/smeltering site soil sample: Monkey = $13 \pm 7\%$ (Roberts et al., 2007); Swine = 14.7% (mean, range <LOD-30.1%) (Rodriguez et al., 1999).



Table 4 summarizes *in vivo* RBA estimates for arsenic in soil collected from or near mining or smelting sites, measured in studies using juvenile swine, mice, or monkeys. Estimates range from a high of $98 \pm 86\%$ in a study of mining-impacted residential soils from the Aspen/Smuggler NPL site, conducted in juvenile swine (Casteel et al., 1997)⁷, to a low of $5 \pm 4\%$ in a study of Colorado smelter soil, conducted in monkeys (Roberts et al., 2007). The mean RBA of the 28 values presented in Table 4 is 35%. Values in monkeys (range 5-19%, mean 14.2%, $n = 6$) tend to be lower than values in swine (range 10-98%, mean 40.7%, $n = 19$) and mice (range 31-45%, mean 29.7%, $n = 4$). These data, and the observations discussed in Section 2.2.4.2 regarding methodological concerns with the design of the monkeys studies, suggest that the estimates of RBA of arsenic in soil and dust at the Anaconda Smelter site (Freeman et al., 1995) are likely low.

⁷Per Casteel et al. (1997), recovery of arsenic in urine, feces, and tissues was very low, ranging from 25-35% of the amount given. The authors report "These estimates are based on very low doses of arsenic and are considered to be highly uncertain."

**Table 4. Summary of Relative Oral Bioavailability Estimates for Arsenic in Soil Impacted by Mining or Smelting Activities**

Site Location and Contaminant Source	Arsenic Soil Concentration (ppm)	Model System	Dosing Protocol	Relative Bioavailability Estimate ^a	Reference
Aspen/Smuggler NPL Site (CO) smelter site [mining]	67	Juvenile swine (n = 4 per group)	Soil in 3 dose levels in dough ball for 2x/d for 15 d; urine collected on day 7 and 14	62 ± 55% ^b	Casteel et al., 1997
Composite of soil collected in residential area surrounding ASARCO smelter site, Tacoma, WA [smelting]	1,600 ± 31	Juvenile swine (n = 3 per group)	Soil in 4 dose levels, single dose (25-150 mg soil/kg BW/d); urine collected over 12 hour periods up to 6 days after dosing	78% (mean; 95% lower and upper limits = 56-111%)	U.S. EPA, 1990a
Iron King Mine—Humboldt Smelter Superfund Site, Yavapai County, AZ, from Chaparral Gulch near residential area [mining]	200 (mean)	Juvenile swine (n = 4 per group)	Soil in 3 dose levels in dough ball for 2x/d for 14 d (200-600 mg soil/kg BW/d); urine collected over 48-hr periods, beginning on days 5, 9, and 12	60% (mean; range 57-70%)	Cited by U.S. EPA, 2012a as Casteel and SRC, 2010a
New Jersey Zinc NPL Site (PA) soil composite [smelting]	134 and 110	Juvenile swine (n = 4 per group)	Soil in 3 dose levels in dough ball for 2x/d for 15 d; urine collected on day 7 and 14	52% and 39% respectively ^b	Casteel et al., 1997
Soil stockpile removed from residential properties and stockpiled; Former ASARCO smelter site near Tacoma, WA [smelting]	182 (mean)	Juvenile swine (n = 4 per group)	Soil in 3 dose levels in dough ball for 2x/d for 14 d (220-660 mg soil/kg BW/d); urine collected over 48-hr periods beginning on days 6, 9, and 12	49% (mean; range 46-52%)	Casteel et al., 2012
Along Silver Bow Creek near Butte, MT [mine tailings deposits]	601	Mouse (n = 4 per group)	Soil amended diet for 9 d; cumulative urine collected daily for 10 d	42.9-45.0%	Bradham et al., 2011



Site Location and Contamination Source	Arsenic Soil Concentration (ppm)	Model System	Dosing Protocol	Relative Bioavailability Estimate	Reference
Along Silver Bow Creek near Butte, MT [mine tailings deposits] ^d	626	Juvenile swine (n = 4 per group)	Soil in 2 dose levels in dough ball for 2x/d for 14 d (93-183 mg soil/kg BW/d); urine collected over 48-hr periods beginning on days 6, 9, and 12	44% (mean; range 41-50%)	Casteel et al., 2009
Along Silver Bow Creek near Butte, MT [mine tailings deposits] ^e	1,513	Mouse (n = 4 per group)	Soil amended diet for 9 d; cumulative urine collected daily for 10 d	42.9%	Bradham et al., 2011
Flood plain of Silver Bow Creek, five miles west of Butte, MT [mine tailings deposits] ^e	1,540 (mean)	Juvenile swine (n = 4 per group)	Soil in 3 dose levels in dough ball for 2x/d for 14 d (27-79 mg soil/kg BW/d); urine collected over 48-hr periods beginning on days 6, 9, and 12	42%	Cited by U.S. EPA, 2012a as Casteel and SRC, 2010c
Bingham Creek (Kennecott South) NPL Site (UT) channel soil [mining]	149	Juvenile swine (n = 4 per group)	Soil in 3 dose levels in dough ball for 2x/d for 15 d; urine collected on day 7 and 14	37 ± 19% ^b	Casteel et al., 1997
Murray Smelter NPL Site (UT) soil [smelting]	310	Juvenile swine (n = 4 per group)	Soil in 3 dose levels in dough ball for 2x/d for 15 d; urine collected on day 7 and 14	34 ± 3% ^b	Casteel et al., 1997
Residential sites affected by mining or smelting activity [mining/smelting]	280-990 (n=8)	Mouse (n = 4 per group)	Soil amended diet for 9 d; cumulative urine collected daily for 10 d	31.0% (mean; range 11.1-52.8%)	Bradham et al., 2011
Vasquez Boulevard and I-70 Superfund site (CO) residential soil composite [smelting]	312-983 (n = 5)	Juvenile swine (n = 4 per group)	Soil in 3 dose levels in dough ball for 2x/d for 12 d; urine collected over 48-hr periods, beginning on days 6, 8, and 10	31% (mean; range 18-45%)	Casteel et al., 2001
California mine tailings	100-1000	Juvenile swine	Soil in 3 dose levels in dough ball for 2x/d for 14 d; urine collected over 48-hr periods, beginning on days 6, 9, and 12	31% (mean; range 18-45%)	Casteel et al., 2001



Site Location and Contamination Source	Arsenic Soil Concentration (ppm)	Model System	Dosing Protocol	Relative Bioavailability Estimate ^a	Reference
Silver Bow Creek/ Butte Area NPL Site (MT) soil composite collected from a residential property located adjacent to a railroad grade	367	Juvenile swine (n = 4 per group)	Soil in 3 dose levels in dough ball for 2x/d for 12 d; urine collected over 48-hr periods, beginning on days 6, 8, and 10	17-24% (mean) [†]	Casteel et al., 2003a,b; U.S. EPA, 2010
Colorado smelter composite soil [smelting]	"at least 100"	Cynomolgus monkey (4-5 kg BW; n = 5 per group)	Fasted ; single administration of 1 soil dose in slurry in water via gavage (soil mass did not exceed 1000 mg/kg BW); urine collected for 4	18 ± 6%	Roberts et al., 2001
Western U.S. mining/smelter site ^b	233-17,500 (n=10)	Juvenile swine (n = 5 per group)	Soil in 3 dose levels in dough ball for 2x/d for 12 d (23-30 mg-soil/dose adjusted based on growth); urine collected over 24-hr periods every 3 d thereafter for 5 collection periods	<LOD-30.1%	Rodriguez et al., 1999



Site Location and Contamination Source	Arsenic Soil Concentration (ppm)	Model System	Dosing Protocol	Relative Bioavailability Estimate ^a	Reference
Western iron slag soil [mining]	"at least 100"	Cynomolgus monkey (4-5 kg BW; n = 5 per group)	Fasted ; single administration of 1 soil dose in slurry in water via gavage (soil mass did not exceed 1000 mg/kg BW); urine collected for 4 days	13 ± 7%	Roberts et al., 2007
Butte NPL Site (MT) soil composite [mining, smelting]	238	Juvenile swine (n = 4 per group)	Soil in 3 dose levels in dough ball for 2x/d for 15 d; urine collected on day 7 and 14	10 ± 5% ^b	Casteel et al., 1997
Colorado smelter soil [smelting]	"at least 100"	Cynomolgus monkey (4-5 kg BW; n = 5 per group)	Fasted ; single administration of 1 soil dose in slurry in water via gavage (soil mass did not exceed 1000 mg/kg BW); urine collected for 4 days	5 ± 4%	Roberts et al., 2007

^a Bioavailability of arsenic in test substance (e.g., soil) relative to sodium arsenate in drinking water.

^b Recovery of arsenic in urine, feces, and tissues ranged from 25-35% of amount given (Casteel et al., 1997)

^c Casteel et al. (1997) reports "These estimates are based on very low doses of arsenic and are considered to be highly uncertain."

^d National Institute of Standards and Technology (NIST) Standard Reference Material 2710 (NIST, 2003)

^e National Institute of Standards and Technology (NIST) Standard Reference Material 2710a.

^f Presented in Casteel et al. (2003a) as 22% (range 17-29%); according to Casteel et al. (2003b) this method was "known to yield low recovery of methyl metabolites." Casteel et al. (2003b) reanalyzed the urine samples using a revised analytical procedure "known to yield good recovery of all urinary metabolites," yielding an estimate of 27% (range 21-35%). U.S. EPA (2010) recalculated estimates of 24% ± 2% and 23%, respectively.

^g Presented in Casteel et al. (2003a) as 17% (range 14-22%); according to Casteel et al. (2003b) this method was "known to yield low recovery of methyl metabolites." Casteel et al. (2003b) reanalyzed the urine samples using a revised analytical procedure "known to yield good recovery of all urinary metabolites," yielding an estimate of 22% (range 17-28%). U.S. EPA (2010) recalculated estimates of 18% ± 3% and 20%, respectively.

^h No specific sample location was given. However, it is described by Rodriquez et al. (1999) as "Two matrices were collected for this study from a typical



mining/smelter site in the western U.S. where wastes were deposited between 20 and 50 years ago. These aged and weathered wastes included a calcine material (a waste product which results from the roasting and smelting of arsenopyrite ore for the extraction of arsenic) and an iron slag material (a waste product that results from the smelting of ores for lead which is also high in iron)...Mineralogical composition of one calcine (soil 4) and one slag (soil 9) was determined by microprobe analysis for the various and arsenic-bearing solid phases. Soil 4 contained 38% of total arsenic as an arsenic jarosite analogue and 60% arsenic associated with Fe and Mn oxides. Soil 9 contained 17% of total arsenic as an arsenic jarosite analogue, 53% associated with Fe and Mn oxides, and 30% of total arsenic associated with lead oxide."

April 12, 2013



2.2.5 *Exposure Duration (ED_a and ED_c)*

CDM (1996) assumed the following exposure durations:

- RME adult: 24 yr
- RME child: 6 yr
- CTE adult: 7 yr
- CTE child: 2 yr

These are U.S. EPA default assumptions for the RME and CTE scenarios (U.S. EPA, 1993a). Both the RME value of 30 years and the CTE value of 9 years are based on data summarized in U.S. EPA's *Exposure Factors Handbook*⁸ in which the average length of residence in the same house by people who own their own home was estimated to be 9 years and the 90th percentile was estimated to be 30 years. In the current *Exposure Factors Handbook* (U.S. EPA, 2011b), the recommended values for "residential occupancy period" are a mean of 12 years and an upperbound (95th percentile) of 33 years.

Based on these and site-specific information suggesting a relatively longer residence time for people who live in the Opportunity Community, the RME ED assumptions used in CDM (1996) will not overestimate site-related risks and may underestimate risks for some members of the population.

2.2.6 *Toxicity Criteria*

The oral cancer slope factor (SF_o) for arsenic applied in the CDM (1996) HHRA was 1.5 (mg/kg-d)⁻¹. This value has not changed, and is U.S. EPA's SF_o for inorganic arsenic (U.S. EPA, 2012c). Inorganic arsenic, including arsenic acid, arsenic pentoxide, and sodium arsenate, is classified by U.S. EPA as a known human carcinogen. The slope factor is based on increased lung cancer mortality in multiple human populations exposed to arsenic via inhalation, including in studies of smelter workers (in Tacoma, WA and Anaconda), as well as evidence of increased mortality from multiple internal organ cancers (liver, kidney, lung, bladder, and an increased incidence of skin cancer) in human populations consuming drinking water high in inorganic arsenic.

Because this value has not changed, it does not affect the recalculated site-related risks and soil cleanup levels.

2.3 *Exposure Pathways Not Considered*

In order to develop an estimate of dose, all relevant exposure pathways need to be evaluated. As described above, the soil cleanup level incorporates only two exposure pathways: soil ingestion and ingestion of interior dust. Based on a site visit to Opportunity in December 2012, the following are plausible exposure pathways that should have been included. They were not included for the reasons noted below, specified in the CDM (1996) document:

- *Dermal contact with soil or dust:* Not included because exposure through this pathway was not expected to contribute significantly. Specifically, CDM (1996) states (p. 3-19), "Only limited data are available on the rate at which metals cross the skin into the blood from soil or dust particles...uptake of metals across skin, especially from soil, is generally believed to be minor." And further, "It is expected that residents...might have dermal contact with contaminated soil. Only limited data are available on the rate at which metals cross the skin into the blood from soil

⁸ The estimates in U.S. EPA (1993a) are based on the 1990 version of the *Exposure Factors Handbook*.



or dust particles; therefore, dermal exposure to metals was not included in the quantitative assessment. It is not considered likely that omission of this pathway causes a significant underestimate of risk because uptake of metals across the skin, especially from soil, is generally believed to be minor.”

- *Inhalation of soil or dust:* Not included because exposure through this pathway was not expected to contribute significantly. Specifically, CDM (1996) states (p. 3-16), “Monitoring data indicate that levels of arsenic and lead in air are below current regulatory limits (Life Systems 1993). Therefore, inhalation of particulate matter released by wind erosion is not assessed quantitatively for residents or commercial workers.”
- *Ingestion of fruits and vegetables:* Not included because exposure through this pathway was not expected to contribute significantly. Specifically, CDM (1996) states (p. 3-7), “Residents may have private gardens in which fruits and vegetables are grown for personal consumption. Anaconda resident survey responses indicate consumption of locally grown fruits and vegetables is minimal (Bornschein, 1993)” (p. 3-7). Further, CDM (1996) states (p. 3-16), “...fruits and vegetables may take up chemicals from the soil into the edible portion of the plant. However, as described in the HHRA for the Mine Flooding OU, Silver Bow Creek/ Butte NPL Site, exposure through this pathway is not expected to contribute significantly to site-related risks, and is, therefore, not further evaluated in this risk assessment.”
- *Ingestion of locally raised meats:* Not included because exposure through this pathway was not expected to contribute significantly. Specifically, CDM (1996) states (p. 3-7), “Livestock production in Deer Lodge County is relatively low compared to other Montana counties; Deer Lodge County ranks as 53 out of 56 counties for beef production (personal communication, Montana Agriculture Line 8/3/94). Farms may have cattle, sheep, and hogs; however, there are typically no more than 2 animals per farm. Chickens are raised on most farms in the area. It is estimated that consumption of locally raised beef is low, as the majority of cattle raised are sold out of state (personal communication, Montana Agriculture Line, 8/3/94). Based on this information, it appears that exposure to arsenic and lead through the ingestion of local contaminated livestock is negligible. This assumption is supported by Anaconda resident survey responses (Bornschein, 1993), which also indicated negligible consumption of locally grown livestock. Moreover, analyses in the Streamside Tailings (SST) OU HHRA (CDM Inc. 1994) indicates that, even if local livestock are consumed, exposure to arsenic and lead through this pathway is not expected to be significant due to minimal concentrations sequestered in tissue.”

Further, CDM (1996) states (p. 3-17), “Livestock could, in theory, take up arsenic and/or lead from ingested soil and food and sequester these chemicals in their tissues. However, information presented in the SST OU HHRA indicates that this is unlikely to occur in significant amounts. Additionally, local residents consume little locally grown livestock. Exposure through this pathway is expected to be negligible for arsenic and lead even where local livestock is consumed based on information presented in Section 3.1.2.1. This pathway is not likely to significantly contribute to site-related risks and is, therefore, not further assessed in this HHRA.”

- *Ingestion of or dermal contact with surface water:* Not included because exposure through this pathway was not expected to contribute significantly. CDM (1996) states (p. 3-18), “Area residents might visit affected creeks and be exposed to surface water through incidental ingestion during wading and other water play activities. Exposure to arsenic and lead might also occur through aquatic recreation in a small pool near Opportunity Ponds. It seems unlikely that such exposures would be associated with significant risks, based on results of the risk assessment recently completed for the SST OU of the Silver Bow Creek NPL Site (CDM Inc. 1994). Surface



water and sediment are heavily contaminated with arsenic and metals in this OU, yet even conservative estimates of potential exposures were not associated with significant risk. Risk-based screening concentrations are developed in Section 6.0 for this exposure pathway."

Further, CDM (1996) states (p. 3-18), "Only recreational users of surface water within the study area would be potentially exposed through this pathway. Lead is not expected to be significantly absorbed across the skin and several risk assessments performed for sites within the Clark Fork Basin have concluded that dermal exposure is insignificant for this metal. Dissolved arsenic in surface water may, however, be absorbed to some extent, although significant exposures are not expected based on results of the SST OU risk assessment (CDM Inc. 1994). This pathway is addressed using risk-based screening levels developed in Section 6.0."

And CDM (1996) states (p. 3-19), "Potential exposures for recreational visitors should occur during visits to surface water in the study area. Incidental ingestion of sediments might occur in much the same way as incidental ingestion of soils. However, recreational visitors are assumed to spend the majority of their time in the water, where sediments are not expected to adhere to skin. Additionally, visitors are assumed to bathe following swimming. Therefore, this HHRA assumes that contact with sediments would be minimal. This pathway is, therefore, considered insignificant and exposure to recreational users is not quantified in this HHRA."

- *Ingestion of fish:* Not included because exposure through this pathway was not expected to contribute significantly. CDM (1996) states (p. 3-17), "...Current or future residents and recreational users could be exposed through ingestion of these fish. Although this is a plausible exposure pathway, screening level calculations presented in Life Systems (1993) indicate that risks resulting from fish ingestion would be very low. Therefore, exposure from ingestion of contaminated fish is not evaluated further in this HHRA."
- *Ingestion of drinking (ground) water, Dermal contact with groundwater, Ingestion of or dermal contact with sediment.* Not included but reason for exclusion not specified.

Information from surveys of Anaconda residents suggest that many of these exposure pathways (e.g., ingestion of fruits and vegetables) are complete for at least some members of the population and should be considered, or that residents engaged in relevant practices in the past but discontinued them out of concerns about potential soil contamination (e.g., growing fruits and vegetables or raising livestock), current U.S. EPA guidance (e.g., U.S. EPA, 2004a; U.S. EPA, 1996b) also suggests that dermal contact with soil/dust and inhalation of soil particulates should be considered in deriving cleanup levels for soil at a site with residential exposures. Exclusion of these pathways results in an incomplete assessment of potential site-related risks and will underestimate the cancer risk using U.S. EPA methodology.

3.0 RECALCULATION OF SITE-RELATED RISKS AND SOIL SCREENING LEVELS

3.1 Quantification of Exposure

I have been asked whether the action level for residential soil established in the Anaconda Smelter NPL ROD was developed in a manner that reflects valid methodologies for predicting exposure and risk, and whether the action levels are appropriately health protective according to U.S. EPA risk assessment practices. In Section 2.0, I review the approach that was used to establish the action level. Based on my critical review of the U.S. EPA Baseline HHRA and knowledge of the Anaconda site, I reevaluate site-related risks and recalculate a soil cleanup level: in Sections 3.1, 3.2, and 3.3, I discuss the revised exposure assumptions for the soil and dust ingestion pathways, as well as



equations and assumptions for other pathways that were not included in the Baseline HHRA but are evaluated here.

Site-related risks were recalculated based on recently collected soil and groundwater data, revised exposure assumptions for the soil and dust ingestion pathways, and additional exposure pathways that were assumed to be complete. These updates are described below.

3.1.1 Estimation of Exposure Point Concentrations

In June 2012, soil and groundwater sample were collected from residential properties in the Opportunity community and analyzed for arsenic. These data were used to calculate exposure point concentrations (EPCs) used to estimate intake of arsenic. Table 5 summarizes these data.

Table 5. Summary of Soil and Groundwater Sampling Data for Arsenic Collected in the Opportunity Community in June 2012

Medium	Depth Interval	Sample Count	Arsenic Concentration Range (mg/kg)	Arsenic Concentration Average and Standard Deviation (mg/kg)
Soil	2-6"	66	7.66-872	140.9 ± 144.4
Soil	6-12"	66	7.38-611	116.0 ± 94.3
Soil	12-24"	18	6.35-181	53.0 ± 48.0
Soil	24-36"	60	1.66-199	19.8 ± 28.7
Soil	36-48"	14	1.86-40.2	9.38 ± 10.3
Soil	48-60"	23	0.994-16.9	5.44 ± 5.25
Groundwater	---	30	0.311-31.4	6.88 ± 7.83

Per U.S. EPA risk assessment guidance (U.S. EPA, 1989; 1992a), the 95 percent upper confidence limit (95% UCL) of the arithmetic mean was used as an estimate of the contaminant's arithmetic average concentration in each river segment for the RME scenario. Use of the 95% UCL provides reasonable confidence that the true average in each exposure area will not be underestimated. Consistent with U.S. EPA guidance, if the calculated 95% UCL exceeded the maximum detected concentration in a given medium, the maximum detected concentration is used (U.S. EPA, 1989; 1992a).

The following assumptions were made for purposes of selecting EPCs for the various potential exposure media:

- **Concentrations in Surface Soil.** Typically, the top 2 cm of soil is assumed to be the depth of soil where direct contact predominantly occurs (U.S. EPA, 1996b). For purposes of this assessment, the EPC for surface soil was calculated based on soil data collected in Opportunity in June 2012 from the 0-2" depth interval.
- **Concentrations in Subsurface Soil, for Estimating Uptake into Produce.** Roots of vegetables



and other garden produce were assumed to uptake arsenic from the shallow subsurface soil. For purposes of this assessment, the EPC for subsurface soil was calculated based on soil data collected in Opportunity in June 2012 from the 2-6" and 6-12" depth intervals.

- **Concentrations in Sediment:** No sampling data for sediments in creeks near Opportunity were identified. Consequently, for the purposes of this assessment, the EPC for sediment was calculated based on soil data collected in Opportunity in June 2012 from the 0-2" depth interval.
- **Concentrations in Ground and Surface Water:** It was assumed that incidental contact with ground or surface water could occur. No sampling data for surface water in creeks near Opportunity were identified. Consequently, for the purposes of this assessment, the EPC for the ground and surface water contact pathways was calculated based on the groundwater data collected in Opportunity in June 2012.

EPCs used in the HHRA are summarized in Table 6.

Table 6. Exposure Point Concentrations (EPCs) Used in the Revised HHRA for the Opportunity, Montana Community

Media	Sample Count	Maximum Concentration	EPC
Subsurface Soil	132	872 ppm	155 ppm
Sediment	66	1,420 ppm	184 ppm
Groundwater/ Surface Water	30	31.4 ppb	15.6 ppb

3.1.2 Additional Complete Exposure Pathways

The contribution of a number of additional exposure pathways excluded in the Baseline HHRA to total arsenic exposure was evaluated. These pathways, and the rationale for their inclusion in the revised HHRA, are as follows:

- **Dermal contact with soil or dust.** Data collected in the Opportunity Community in June 2012 show arsenic contamination of surface soils. Consequently, this exposure pathway is assumed to be complete. In addition, dermal absorption factors are available to estimate uptake of arsenic across skin: U.S. EPA's *Supplemental Guidance for Dermal Risk Assessment* (U.S. EPA, 2004a) recommends assuming a dermal absorption fraction from soil for arsenic of 0.03.
- **Inhalation of soil particulates.** As discussed, data collected in the Opportunity Community in June 2012 show arsenic contamination of surface soils. U.S. EPA's *Soil Screening Guidance*, which is intended to support calculation of cleanup levels for contaminated soils at sites on the NPL with future residential land use, identifies inhalation of volatiles and fugitive dusts as one of the three most common routes of exposure to environmental contaminants in the residential setting (the other two are direct ingestion and ingestion of potable ground water) (U.S. EPA, 1996b). Consequently, this exposure pathway is assumed to be complete. In addition, the *Soil Screening Guidance* provides exposure equations and default assumptions to support estimation of particulate emissions from soils.



- **Ingestion of fruits and vegetables.** In the Baseline HHRA, this pathway was not evaluated in part because “Anaconda resident survey responses indicate consumption of locally grown fruits and vegetables is minimal” (Section 2.3, above). However, information gathered from Opportunity residents indicates that many of them currently, or have in the past, grow and consume vegetables from backyard gardens, and some also grow and consume fruit from fruit trees, raspberry bushes, and strawberry plants. Consequently, this exposure pathway is assumed to be complete.
- **Ingestion of locally raised meat.** In the Baseline HHRA, this pathway was not evaluated in part because “Livestock production in Deer Lodge County is relatively low compared to other Montana counties...there are typically no more than 2 animals per farm” (Section 2.3, above). However, information gathered from Opportunity residents indicates that a number of them currently, or have in the past, raise and consume chickens and chicken eggs, and several have also raised cattle or pigs. In addition, a number of Opportunity residents report consuming locally caught wild game including venison, elk, and ducks. Consequently, this exposure pathway is assumed to be complete.
- **Ingestion of and dermal contact with ground or surface water and ingestion of or dermal contact with sediment.** Several creeks run adjacent to the Opportunity Community. As a result, it is possible that local residents may visit the creeks and be exposed to surface water through incidental ingestion or dermal contact while wading or splashing in the creek. Consequently, these exposure pathways are assumed to be complete.

In general, for each pathway, the lifetime average daily dose (LADD), in units of milligrams of arsenic per kilogram of body weight per day (mg/kg-d), was calculated based on the assumed concentration in the exposure medium, the contact rate, and the frequency and duration of exposure, as follows:

$$LADD \left(\frac{mg}{kg \times d} \right) = \frac{C \left(\frac{mg}{kg} \right) \times Contact\ rate \left(\frac{kg}{d} \right) \times Exposure\ frequency \left(\frac{d}{yr} \right) \times Exposure\ duration\ (yr)}{Body\ weight\ (kg) \times Averaging\ time \left(\frac{70\ yr \times 365\ d}{1\ yr} \right)}$$

Pathway-specific lifetime excess cancer risks were then calculated by multiplying each LADD by the appropriate pathway-specific toxicity criterion (the oral cancer slope factor for ingestion pathways, the dermal slope factor for dermal contact pathways, or the inhalation unit risk value for the particulate inhalation pathway), for example:

$$Lifetime\ excess\ cancer\ risk = LADD\ (mg/kg-d) \times SF\ (mg/kg-d)^{-1}$$

For arsenic, the following toxicity criteria were used:

- **Oral slope factor (SF_o):** 1.5 (mg/kg-d)⁻¹ (U.S. EPA, 2012c)
- **Dermal slope factor (SF_d):** 1.5 (mg/kg-d)⁻¹ (U.S. EPA, 2012c). In general, it is recommended that dermal slope factors be calculated by adjusting an administered dose slope factor (i.e., the oral slope factor) to an absorbed dose slope factor (i.e., the dermal slope factor) by dividing the administered dose slope factor by the fraction of the contaminant absorbed in the gastrointestinal tract in the critical toxicity study (U.S. EPA, 1992b). However, in recommending a dermal value for arsenic, U.S. EPA assumed that the majority of the ingested dose in the studies upon which the oral slope factor are based (e.g., soluble arsenic in drinking water) is gastrointestinally absorbed. Consequently, U.S. EPA (1992b) does not recommend adjusting the oral slope factor for arsenic, but to also use this value as the dermal slope factor.



- **Inhalation unit risk factor (UR):** $0.0043 (\mu\text{g}/\text{m}^3)^{-1}$ (U.S. EPA, 2012c). A UR is the upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of $1 \mu\text{g}/\text{m}^3$ in air (U.S. EPA, 2012e).

Exposure parameters and assumptions are listed in Table 7.

Table 7. Exposure Parameters Used in the Risk Calculations for the Residential Scenario at the Opportunity, MT Site

$IR_{\text{sed (c or a)}}$	Ingestion rate of soil, child or adults	Child: 100 mg/event Adult: 50 mg/event	U.S. EPA, 1991; U.S. EPA 2011b; Professional judgment
IR_{water}	Incidental ingestion rate of surface or groundwater	0.05 L/d	U.S. EPA, 1995
FI_{soil}	Fraction of soil and dust ingested or contacted that is soil	0.45 (unitless)	CDM, 1996
FI_{dust}	Fraction of soil and dust ingested or contacted that is dust	0.55 (unitless)	CDM, 1996
RBA_{soil}	Relative oral bioavailability factor for soil	20.3%	Freeman et al., 1995
RBA_{dust}	Relative oral bioavailability factor for dust	29.1%	Freeman et al., 1995
RBA_{sed}	Relative oral bioavailability factor, sediment	20.3%	Freeman et al., 1995 (same as soil)
$SA_{\text{soil (c or a)}}$	Skin surface area for dermal contact with soil or dust, child or adult	Child: 1,720 cm ² /event Adult: 4,825 cm ² /event	U.S. EPA, 1992b; U.S. EPA, 2011b
$SA_{\text{sed (c or a)}}$	Skin surface area for dermal contact with sediment, child or adult	Child: 1,460 cm ² /event Adult: 4,560 cm ² /event	U.S. EPA, 2011b
$SA_{\text{water (c or a)}}$	Skin surface area for incidental dermal contact with surface or groundwater, child or adult	Child: 2,830 cm ² /event Adult: 10,920 cm ² /event	U.S. EPA, 2011b
$AF_{\text{soil (c or a)}}$	Skin adherence factor for soil, child or adult	Child: 0.12 mg/cm ² Adult: 0.01 mg/cm ²	U.S. EPA, 2004a
$AF_{\text{dust (c or a)}}$	Skin adherence factor for dust, child or adult	Child: 0.01 mg/cm ² Adult: 0.004 mg/cm ²	U.S. EPA, 2004a; Professional judgment
$AF_{\text{sed (c or a)}}$	Skin adherence factor for sediment, child or adult	Child: 0.18 mg/cm ² Adult: 0.18 mg/cm ²	U.S. EPA, 2000a
$ABS_{\text{soil (c or a)}}$	Dermal absorption fraction of arsenic from soil or sediment	0.032 (unitless)	U.S. EPA, 2004a
EF	Exposure frequency, all but dermal contact with soil, or incidental exposure to surface or groundwater or to sediment	350 events or days/year	U.S. EPA, 1996b; U.S. EPA, 2012d
$EF_{\text{soil (c or a)}}$	Exposure frequency, direct contact with soil, for child or adult	Child: 130 days/year Adult: 48 days/year	Professional judgment
$EF_{\text{water or sediment (c or a)}}$	Exposure frequency, incidental exposure to surface or groundwater or to sediment, for child or adult	Child: 18 days or events/year Adult: 6 days or events/year	Professional judgment



Parameter	Description	Value	Source
$BW_{(c \text{ or } a)}$	Body weight, child or adult	Child: 15 kg Adult: 70 kg	U.S. EPA, 1996b; U.S. EPA, 2012d
At	Averaging time	25,550 days	U.S. EPA, 1996b; U.S. EPA, 2012d
K_p	Percutaneous absorption factor	0.001 cm/hr	U.S. EPA, 1992b
PEF	Particulate emission factor	$1.32 \times 10^9 \text{ m}^2/\text{kg}$	U.S. EPA, 1996b
$ET_{(c \text{ or } a)}$	Exposure time, incidental dermal contact with surface or groundwater or with sediment, child or adult	Child: 1 hour/event Adult: 0.5 hour/event	Professional judgment
Br_{exp}	Arsenic plant/soil bioconcentration factor for above ground exposed produce from root uptake	0.026 (mg/kg dry weight (DW)) / (mg/kg soil)	Cobb et al., 2000; Ramirez-Andreotta et al., 2013
Br_{agg}	Arsenic plant/soil bioconcentration factor for above ground protected produce (e.g., fruits, nuts) from root uptake	0.006 (mg/kg dry weight (DW)) / (mg/kg soil)	Baes et al., 1985
Br_{bg}	Arsenic plant/soil bioconcentration factor for below ground produce from root uptake	0.0036 (mg/kg dry weight (DW)) / (mg/kg soil)	Cobb et al., 2000; Ramirez-Andreotta et al., 2013
$CF_{d-w(ge)}$	Dry-to-wet weight conversion factor for exposed (above ground) produce	0.126 kg DW/kg fresh weight	Baes et al., 1985
$CF_{d-w(ge)'}^*$	Dry-to-wet weight conversion factor for protected (above ground) produce	0.222 kg DW/kg fresh weight	Baes et al., 1985
$CF_{d-w(bg)}$	Dry-to-wet weight conversion factor for below ground produce	0.222 kg DW/kg fresh weight	Baes et al., 1985
$IR_{exp(c \text{ or } a)}$	Ingestion rate of above ground exposed produce, child or adult	Child: 0.00077 kg DW/d Adult: 0.00032 kg DW/d	U.S. EPA, 2011b
$IR_{agg(c \text{ or } a)}$	Ingestion rate of above ground protected produce, child or adult	Child: 0.0015 kg DW/d Adult: 0.00061 kg DW/d	U.S. EPA, 2011b
$IR_{bg(c \text{ or } a)}$	Ingestion rate of below ground produce, child or adult	Child: 0.00023 kg DW/d Adult: 0.00014 kg DW/d	U.S. EPA, 2011b
$RBA_{veg-ag,e}$	Relative bioavailability of arsenic in ingested above ground, exposed produce	50%	Juhasz et al., 2008
$RBA_{veg-ag,e}'$	Relative bioavailability of arsenic in ingested above ground, protected produce	75%	Juhasz et al., 2008
RBA_{veg-bg}	Relative bioavailability of arsenic in ingested below	100%	Juhasz et al., 2008

April 12, 2013

30



Exposure Parameter	Description	Value	Source
IR _{soil-cattle}	Quantity of soil eaten by beef cattle each day	0.002 kg soil/kg BW-d	Mayland et al., 1977
B _{soil}	Arsenic plant/soil bioconcentration factor for forage from root uptake	0.036(mg/kg dry weight (DW))/(mg/kg soil)	U.S. EPA, 2005
IR _{forage-cattle}	Quantity of forage ingested by beef cattle per day	0.017 kg forage DW/kg BW-d	NRC, 1987
B _{meat}	Arsenic intake/muscle bioconcentration factor for beef cattle	0.097 (mg/kg muscle)/(mg/kg BW-d)	Bruce et al., 2003
IR _{meat(c or a)}	Consumption rate of beef, child or adult	Child: 0.0012 kg FW/kg-BW-d Adult: 0.00059 kg FW/kg-BW-d	U.S. EPA, 2011b
F _{meat}	Fraction of beef from a contaminated source	Resident: 1 Professional judgment (consumption rate based on home-produced meat)	
CF	Conversion factor, liters per cm ³ or kilograms per g	0.001 L/cm ³ or 0.001 kg/g	---

3.1.2.1 Contributions from Soil or Dust

Dermal Contact with Soil or Dust

Uptake from incidental dermal contact with soil or dust was calculated using the following equations.

For soil:

$$\begin{aligned}
 Abs_{soil(c)} &= C_{soil} \times SA_c \times AF_{soil} \times F_{soil} \times ABS \times CF \\
 Abs_{soil(a)} &= C_{soil} \times SA_a \times AF_{soil} \times F_{soil} \times ABS \times CF \\
 Risk_{soil} &= \left(\frac{Abs_{soil(c)} \times EF_c \times ED_c}{BW_c \times AT} + \frac{Abs_{soil(a)} \times EF_a \times ED_a}{BW_a \times AT} \right) \times SF
 \end{aligned}$$

Where $Abs_{soil(c)}$ and $Abs_{soil(a)}$ are the absorbed doses in mg/event for the child and the adult, respectively.

For dust:

$$\begin{aligned}
 Abs_{dust(c)} &= C_{dust} \times SA_c \times AF_{dust} \times F_{dust} \times ABS \times CF \\
 Abs_{dust(a)} &= C_{dust} \times SA_a \times AF_{dust} \times F_{dust} \times ABS \times CF \\
 Risk_{dust} &= \left(\frac{Abs_{dust(c)} \times EF_c \times ED_c}{BW_c \times AT} + \frac{Abs_{dust(a)} \times EF_a \times ED_a}{BW_a \times AT} \right) \times SF
 \end{aligned}$$

Where $Abs_{dust(c)}$ and $Abs_{dust(a)}$ are the absorbed doses in mg/event for the child and the adult, respectively.

Several factors can affect the potential for exposure to arsenic from dermal contact with soil. In general, it is assumed that activities associated with incidental soil ingestion are likely to present opportunities for dermal exposure (U.S. EPA, 1992b), although soil ingestion rates are based on annual average values whereas dermal exposure is typically evaluated on a per-event basis. Overall, it is assumed that dermal contact with soil and dust would be greater during warmer months when people spend more time outdoors and/or the surface area of exposed skin is greater. There is also uncertainty about the residence time of soil or dust on skin, which can affect the total absorption



potential, but it is assumed to roughly correspond to the time between washings, or about 8 to 24 hours (U.S. EPA, 1992b).

A range of values for frequency of exposure to outdoor soil have been proposed (U.S. EPA, 1992b), ranging for adults from 43 days/year (an assumed “typical” value for an adult who gardens or works outside 1 to 2 days/week during the warmer months) to 350 days per year (based on the rationale that in warmer climates, people who actively garden or play outdoors could have contact with soil almost every day). For children, a “typical” value of 130 days per year has been proposed. For this assessment, it is assumed that for adults, the exposure frequency (EF) to soil contact is four times/month (or 48 days/year) and for children it is 2-3 times/week (or 130 days/year). It is assumed that adults and children contact dust 350 days/year.

The assumed skin surface area available for soil or dust contact (SA) is based on data presented in U.S. EPA’s *Dermal Exposure Assessment* guidance (U.S. EPA, 1992b) and *Exposure Factors Handbook* (U.S. EPA, 2011b), according to the following considerations:

- For children, the value (1,720 cm²/event) assumes contact by head, hands, lower arms, feet, and lower legs for 25% of events, and head, hands and lower arms for 75% of events, based on the mean surface area by body part averaged for children ages 2 to 6 (U.S. EPA, 2011b).
- For adults, the value (2,825 cm²/event) assumes contact by head, hands, lower arms, and lower legs for 25% of events, and head and hands for 75% of events (U.S. EPA, 1992b).

The soil- or dust-to-skin adherence factor (AF) describes the mass of soil or dust that adheres to skin per square centimeter of skin surface. Assumed values were drawn from U.S. EPA (2004a), and are based on the following:

- For soil, the adult value is based on the mean value for groundskeepers (0.01 mg/m²) since it was assumed that adults could come in contact with local soils while doing yard or garden work. The child value is based on the average of mean values for children playing in dry soil and children playing in wet soil (0.12 mg/m²).
- For dust, the adult value is assumed to be one-half that for soil (0.005 mg/m²) due to the lack of any other data and the assumption that dust adherence would be less than that of soil. The child value is based on the mean value for children indoors (0.01 mg/m²).

The dermal absorption factor (ABS) describes the uptake of arsenic across skin when in contact with arsenic in soil. The value (0.032) is U.S. EPA’s chemical-specific default for this pathway (U.S. EPA, 2004a).

Inhalation of Soil Particulate

Uptake from inhalation of soil particulate was calculated using the following equation and assumptions:

$$Risk_{soil} = \left(\frac{C_{soil} \times 1000 \frac{\mu g}{mg} \times EF \times ED_c}{PEF \times AT} \right) \times UR$$

The particulate emission factor (PEF) relates the concentration of contaminant in soil to the concentration of dust particles in air. The value assumed is a U.S. EPA default value (1.32 × 10⁹ m³/kg) and is derived from modeling conducted by U.S. EPA that incorporates assumptions about annual average emission rate based on wind erosion (in g/m²-s per kg/m³), fraction of vegetative cover (50%), and annual windspeed (4.69 m/s) (U.S. EPA, 1996b).



The exposure equation results in an estimate of the annual average airborne concentration of arsenic to which an individual is exposed (in $\mu\text{g}/\text{m}^3$). Lifetime excess cancer risk for this pathway is estimated by multiplying this concentration by the inhalation unit risk factor (UR) for arsenic of 0.0043 per $\mu\text{g}/\text{m}^3$ (U.S. EPA, 2012c).

A separate equation to estimate uptake from inhalation of dust was not included due to lack of information on re-entrainment of dust into the air. However, it is assumed that if this pathways were included in the risk assessment, the overall site-related risks would increase slightly (as shown in Section 3.2, inhalation is not a major exposure pathway compared to some other exposure pathways).

Ingestion of Locally Grown Produce

Uptake from ingestion of locally grown produce contaminated by deposition of airborne arsenic or uptake of arsenic from soil (Risk_{veg}) was calculated using the following equations and assumptions.

Separate plant uptake and produce consumption rates were applied for three different categories of produce: aboveground exposed, aboveground protected, and belowground (root) vegetables or fruit. These categories are used because it is assumed that contaminants are taken up from soil or air at different rates into these groups of produce. Per Baes et al. (1985),

Exposed produce (snap beans, tomatoes, apples, etc.) intercept atmospherically depositing material on edible surfaces, but surface areas for exposure are relatively small compared to leafy vegetables. Additionally, edible portions are typically concerned with reproductive functions (fruits and seeds). Protected produce (potatoes, peanuts, citrus fruits, etc.) are not directly exposed to atmospherically depositing material because their growth habit is underground, or if aboveground, the edible portions are protected by pods, shells, or nonedible skins or peels. Typically, edible portions are reproductive or storage organs.

First, the concentration of arsenic in above ground exposed (C_{age}), above ground protected (C_{agp}), and below ground (C_{bg}) produce, in mg/kg wet weight, is calculated:

$$C_{\text{age}} = C_{\text{sdeep}} \times Br_{\text{age}} \times CF_{\text{d-w}(\text{age})}$$

$$C_{\text{agp}} = C_{\text{sdeep}} \times Br_{\text{agp}} \times CF_{\text{d-w}(\text{agp})}$$

$$C_{\text{bg}} = C_{\text{sdeep}} \times Br_{\text{bg}} \times CF_{\text{d-w}(\text{bg})}$$

Then the lifetime average daily dose (LADD) for the child and adult, and the associated cancer risk, are calculated

$$LADD_{\text{veg}(c)} = \left(\frac{[(C_{\text{age}} \times IR_{\text{age}(c)}) + (C_{\text{agp}} \times IR_{\text{agp}(c)}) + (C_{\text{bg}} \times IR_{\text{bg}(c)})] \times RBA_{\text{veg-age}} \times F_{\text{veg}} \times EF \times ED_c}{AT} \right)$$

$$LADD_{\text{veg}(a)} = \left(\frac{[(C_{\text{age}} \times IR_{\text{age}(a)}) + (C_{\text{agp}} \times IR_{\text{agp}(a)}) + (C_{\text{bg}} \times IR_{\text{bg}(a)})] \times RBA_{\text{veg-age}} \times F_{\text{veg}} \times EF \times ED_a}{AT} \right)$$

$$Risk_{\text{veg}} = (LADD_{\text{veg}(c)} + LADD_{\text{veg}(a)}) \times SF_o$$

In this assessment, for estimating concentrations of arsenic in produce, uptake from soil only was assumed—deposition of airborne particulate was not evaluated due to the lack of data on airborne arsenic deposition. Nonetheless, in some cases with sufficient air concentrations, atmospheric deposition can contribute significantly to plant arsenic concentrations, with accumulation of arsenic in both the leaves and storage organs of root crops reported as a result of atmospheric deposition near an active metal smelter (De Temmerman et al., 2012).



The assumed homegrown produce consumption rates were as follows:

- *Consumption rate of aboveground exposed produce (IR_{age}):* Values of 1.36 g/ kg BW-d (fresh weight, converted to 0.171 g /kg BW-d dry weight) for adults and 1.45 g/ kg BW-d (fresh weight, converted to 0.183 g /kg BW-d dry weight) for children were assumed. These values represent the mean per capita intake of all exposed vegetables reported for the U.S. population for ages 20-69 (adults) and 2 to 9 (children) (U.S. EPA, 2011b). Assuming a typical adult body weight of 70 kg, the adult rate equates to 95 g/d (or 3.4 ounces/d), which is equivalent to consumption of about 2 cups of lettuce.
- *Consumption rate of aboveground protected produce (IR_{agg}):* Values of 0.55 g/ kg BW-d (fresh weight, converted to 0.122 g /kg BW-d dry weight) for adults and 1.0 g/ kg BW-d (fresh weight, converted to 0.222 g /kg BW-d dry weight) for children were assumed. These values represent the mean per capita intake of all protected vegetables reported for the U.S. population for ages 20-69 (adults) and 2 to 9 (children) (U.S. EPA, 2011b). Assuming a typical adult body weight of 70 kg, the adult value equates to 38.5 g/d (or 1.4 ounces/d), which is equivalent to consumption of about 1/4 cup of fresh peas.
- *Consumption rate of belowground produce (IR_{bg}):* Values of 1.03 g/ kg BW-d (fresh weight, converted to 0.229 g /kg BW-d dry weight) for adults and 1.95 g/ kg BW-d (fresh weight, converted to 0.433 g /kg BW-d dry weight) for children were assumed. These values represent the mean per capita intake of all belowground produce reported for the U.S. population for ages 20-69 (adults) and 2 to 9 (children) (U.S. EPA, 2011b). Assuming a typical adult body weight of 70 kg, the adult value equates to 72.1 g/d (or 2.5 ounces/d), which is equivalent to consumption of about one carrot.

To estimate which fraction of all consumed produce is from home gardens, it was assumed that on an annual average basis, 25% of all vegetables consumed was from home gardens (F_{veg}).

A literature search was conducted to identify data on uptake of arsenic from soil into produce. In general, authors have observed that leafy vegetables (e.g., lettuce, spinach) take up more arsenic into their edible parts than non-leafy vegetables (e.g., tomatoes, eggplant, beans, peas) (Ramirez-Andreotta et al., 2013). In addition, uptake can vary not only based on the soil concentration, but also based on the dominant inorganic arsenic species in soil (e.g., plants have been shown to preferentially take up arsenate, the dominant species in oxic environments; Ramirez-Andreotta et al., 2013); and soil characteristics such as pH, organic matter, clay content, water regime, and nutrient balance (e.g., uptake of arsenic from sandy soils is much greater than from clay soils; Ramirez-Andreotta et al., 2013).

Because of the potential impact of soil characteristics on plant uptake of arsenic, plant uptake factors were estimated based on data from similar sites, where available. The following studies evaluated plant uptake of arsenic from soils impacted by mining or smelting operations:

- Cobb et al. (2000) evaluated uptake of heavy metals into vegetables grown in soils mixed with mine wastes collected from areas in the Bingham Creek mining district near Salt Lake City, Utah. Plants were grown in a greenhouse, and soils were prepared with a percentage of mine tailing of 0, 25, 50, 75, or 100%, with average arsenic concentrations of 23.3, 187, 196, 303, and 408 ppm, respectively. Bioconcentration factors (BCFs, in units of (mg As/kg plant, DW)/(mg As/kg soil, DW)) were calculated based on concentrations in edible plant parts and in soil, and ranged as follows: Bean = 0.00162-0.00790 (mean 0.00393); Radish = 0.0121-0.0292 (mean 0.0205); Lettuce = 0.00755-0.235 (mean 0.125). Arsenic was not detected in tomatoes (limit of detection = 0.125 mg/kg); assuming arsenic was present in tomatoes at one-half the detection limit resulted



in calculated BCFs for tomatoes ranging from 0.000153-0.00268 (mean 0.000739).

- Ramirez-Andreotta et al. (2013) evaluated plant uptake of arsenic in a controlled greenhouse study (with mean soil concentrations ranging from 27.2 to 533 ppm) and a garden study (with mean soil concentrations ranging from 2.35 to 374 ppm), to characterize the potential uptake of arsenic into homegrown vegetables at residences near the Iron King Mine and Humboldt Smelter Superfund site in southern Arizona. All vegetables in both experiments accumulated arsenic, with a direct correlation between the amount of arsenic in the edible portion of the plant and arsenic in soil for most of the vegetable families including Asteraceae (lettuce; BCF = 0.0478 mg plant DW/mg soil), Brassicaceae (radish, broccoli, kale, cabbage; BCF = 0.0146), Amaranthaceae (beet, Swiss chard, spinach; BCF = 0.00982), and Fabaceae (bean; BCF = 0.00323) families, but not the Solanaceae (tomato, pepper; BCF = 0.00391) and Cucurbitaceae (squash, cucumber; 0.00483) families. Per the authors:

The results suggest that home gardeners neighboring mining operations or mine tailings with elevated arsenic levels should be made aware that arsenic can accumulate considerably in certain vegetables, and in particular, it is recommended that gardeners limit consumption of vegetables from the Asteraceae and Brassicaceae plant families.

Based on these data, the following BCFs were used in the current assessment:

- *Above ground, exposed produce:* 0.026 mg/kg plant (DW)/mg/kg soil (based on the mean of mean values for lettuce, tomatoes, Brassicaceae, Amaranthaceae, Solanaceae, and Cucurbitaceae families from the above studies). This value is consistent with the value presented in Baes et al. (1985) of 0.04.
- *Above ground, protected produce:* 0.0036 mg/kg plant (DW)/mg/kg soil (based on the mean of mean values for beans from the above studies). This value is consistent with the value in Baes et al. (1985) of 0.006.
- *Below ground, root produce:* 0.006 mg/kg plant (DW)/mg/kg soil (based on the value presented in Baes et al. (1985) for below ground produce). A value derived from smelting or mining contaminated soils was not identified.

Juhasz et al. (2008) and Larios et al. (2012) report that, in general, only inorganic arsenic (i.e., arsenite and arsenate) are detected in the edible portion of vegetables, with organic species rarely found; thus, it is appropriate to assume that the species of arsenic in consumed homegrown produce is the same as that upon which the toxicity criteria for arsenic is based (i.e., sodium arsenate in drinking water). However, as with other matrices, not all of the arsenic in produce may be bioavailable. When Juhasz et al. (2008) assessed arsenic bioavailability after ingestion of arsenic-contaminated vegetables based on blood plasma concentrations in swine, between 50-100% of the total administered arsenic dose was estimated to be absorbed and enter the systemic circulation, with mean values of 52% and 50% for chard and lettuce, respectively, 98% for mung bean, and 77% for radish. Based on these data, in this assessment, 50%, 75%, and 100% of the arsenic estimated to be ingested from above ground exposed, above ground protected, and below ground root produce, respectively, was assumed to be bioavailable.



Ingestion of Locally Raised Meat

Exposure to arsenic from ingestion of locally raised meat was calculated assuming uptake into cattle from ingestion of arsenic in soil and forage, using the following equations and assumptions:

$$C_{meat} = [(C_{soil} \times IR_{soil-cattle}) + (C_{soil} \times B_{forage} \times IR_{forage-cattle})] \times B_{meat}$$

$$Risk_{meat} = \left(\frac{C_{meat} \times F_{meat} \times EF \times [(IR_{meat(c)} \times ED_c) + (IR_{meat(a)} \times ED_a)]}{AT} \right) \times SF$$

Estimates of uptake of arsenic into muscle of beef cattle were based on a study by Bruce et al. (2003) in which cattle were grazed in paddocks that had known concentrations of arsenic in soil from contamination by mine tailings. The grazing trial continued for approximately 8 months (237 days) and periodic samplings of blood and biopsy of the liver and muscle from the animals were conducted to monitor the accumulation of metals. The authors cite three possible pathways for cattle to ingest arsenic from the tailings: (1) ingesting pasture plants that have accumulated heavy metals in their leaf and stem tissues, (2) directly ingesting contaminated soil that has adhered to pasture plant surfaces, and (3) either deliberate direct ingestion of tailing material or accidental ingestion during grazing. Dose rates for arsenic in ingested plants and arsenic adhered to plants were calculated based on an estimate of dry matter intake per day (2.5% of body weight per day) and the average weight of the animals during the trial (331 kg). The authors also state that direct ingestion of soil (not associated with plant material) may be up to 10% of the daily dry matter intake, equating to as much as 1 kg of soil per day. Per Bruce et al. (2003), "This is consistent with earlier work done by Thornton and Abrahams (1983), who reported arsenic in soil being a more important contamination pathway than via plant material."

Overall, accumulation of arsenic in cattle was greater in organs such as the liver and kidneys. The measured concentration in muscle, relative to a unit intake of 1 mg/kg-BW-d, was 0.097 (mg/kg-muscle)/(mg/kg-BW-d).

Based on this information, the following values for exposure parameters for this pathway were assumed:

- *Ingestion rate of soil by cattle ($IR_{soil-cattle}$):* 0.002 kg-soil/kg-BW-d. This value is based on the average soil ingestion rate by grazing cattle of 0.825 kg/day, divided by an assumed average body weight of 350 kg; (Mayland et al., 2005).
- *Ingestion rate of forage by cattle ($IR_{forage-cattle}$):* 0.017 kg-forage (DW)/kg-BW-d. This value is based on data from NRC (1987) indicating that an 800 pound (364 kg) animal consumes about 8.1- 9.8 kg dry matter/d and a 1,000 pound (454 kg) animal consumes about 8.8- 11.5 kg dry matter/d. These values are in turn predicted by a number of different models that take into account differences in starting body weight, frame size, and net energy of the feed. These values are equivalent to a range of 0.019-0.027 kg dry matter/kg-d and are consistent with U.S. EPA's *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities* which recommends assuming 11.8 kg total daily dry matter intake by beef cattle (cattle weight unspecified), of which 8.8 kg/d (75%) is forage, 2.5 kg/d (21%) is silage, and 0.47 kg/d (4%) is grain (U.S. EPA 2005a). For these calculations, we assume an average forage ingestion rate of 0.017 kg dry matter/kg-d (0.023 kg \times 75%).
- *Arsenic plant/soil bioconcentration factor for forage (B_{forage}):* 0.036 mg/kg-plant (DW)/mg/kg soil. This is an arsenic-specific value presented in U.S. EPA (2005), and is consistent with the value for uptake of arsenic from soil into above ground exposed produce assumed above of 0.026



mg/kg plant (DW)/mg/kg soil.

- *Arsenic intake/ muscle bioconcentration factor for cattle (B_{meat}):* 0.097 mg/kg-plant (DW)/mg/kg soil. This is based on the measured concentration in muscle, relative to a unit intake of 1 mg/kg BW-d, reported in Bruce et al. (2003).

The consumption rate of beef was based on the mean per capita intake of home-produced meats reported for U.S. populations that farm or raise animals (U.S. EPA, 2011b). These values were as follows:

- *Consumption rate of aboveground exposed meat (IR_{meat}):* Values of 0.59 g/kg-BW-d (fresh weight) for adults and 1.2 g/kg-BW-d (fresh weight) for children were assumed. These values represent the mean per capita intake of home-produced meats reported for U.S. populations that farm or raise animals for ages 20-69 (adults) and 2 to 9 (children) (U.S. EPA, 2011b). Assuming a typical adult body weight of 70 kg, the adult value equates to 41 g/d (or 1.5 ounces/d), which is equivalent to consumption of about 10 ounces of homegrown meat per week.

Since this consumption rate is based on data for consumption of home-produced meats, it is assumed that 100% of the home-produced meat consumed is from a contaminated source (F_{meat}).

3.1.2.2 Contributions from Surface or Ground Water and Sediment

Incidental Ingestion of Surface or Ground Water

Uptake from incidental ingestion of surface or ground water was calculated using the following equation and assumptions:

$$Abs_{water} = C_{water} \times IR_{water} \times BAF$$

$$Risk_{water} = \left(\frac{Abs_{water} \times EF_{water(c)} \times ED_c}{BW_c \times AT} + \frac{Abs_{water} \times EF_{water(a)} \times ED_a}{BW_a \times AT} \right) \times SF$$

Where Abs_{water} is the absorbed dose in mg/d.

The incidental ingestion rate of surface or ground water not used as a drinking water source was assumed to be 0.05 L/d, the U.S. EPA default incidental water ingestion rate (U.S. EPA, 1989). This is equivalent to about 1.7 fluid ounces or 3.4 tablespoons per exposure event.

The relative bioavailability (RBA) of arsenic in ingested water was assumed to be 100% (i.e., the same as in the studies that are the basis for the toxicity criterion).

It is assumed that for adults, based on professional judgment and the assumption that residents would occasionally but infrequently contact surface water, the exposure frequency (EF) to water contact is six times/year (one day per month for six months). For children, EF was assumed to be 18 times/year (two days per month for six months plus one day per month for six months).



Incidental Dermal Contact with Surface or Ground Water

Uptake from incidental dermal contact with surface or ground water was calculated using the following equation and assumptions:

$$\begin{aligned}
 Abs_{water(c)} &= C_{water} \times SA_c \times Kp \times CF \times ET \\
 Abs_{water(a)} &= C_{water} \times SA_a \times Kp \times CF \times ET \\
 Risk_{water} &= \left(\frac{Abs_{water(c)} \times EF_{water(c)} \times ED_c}{BW_c \times AT} + \frac{Abs_{water(a)} \times EF_{water(a)} \times ED_a}{BW_a \times AT} \right) \times SF
 \end{aligned}$$

Where $Abs_{water(c)}$ and $Abs_{water(a)}$ are the absorbed doses in mg/event for the child and the adult, respectively.

The skin surface area available for water contact (SA) is based on data presented in U.S. EPA's *Exposure Factors Handbook* (U.S. EPA, 2011b), and assumes contact during wading or contact from the shore. It is based on the following:

- For adults, the value (4,560 cm²/event) assumes contact by hands, lower arms, lower legs, and feet for 50% of events, and hands and lower arms for 50% of events, based on mean surface area by body part averaged for males and females.
- For children, the value (1,750 cm²/event) assumes contact by head, hands, lower arms, feet, and lower legs for 50% of events, and hands and lower arms for 50% of events, based on mean surface area by body part averaged for children ages 2 to 6.

The percutaneous absorption factor (Kp) was assumed to be 0.001 cm/hr and is a U.S. EPA default value based on the assumption that water-soluble compounds have a human skin permeability constant that is unlikely to exceed 0.001 cm/hr (U.S. EPA, 1992b).

It is assumed that for adults, the exposure time (ET) to water contact is one-half hour per event and for children it is one hour per event.

Like the incidental ingestion pathway, it is assumed that for adults, based on professional judgment and the assumption that residents would occasionally but infrequently contact surface water, that the exposure frequency (EF) to water contact is six times/year (one day per month for six months) and for children it is 18 times/year (two days per month for six months and one day per month for six months).

Incidental Ingestion of Sediment

Uptake from incidental ingestion of sediment was calculated using the following equations and assumptions:

$$\begin{aligned}
 Abs_{sed-ing(c)} &= C_{sed} \times IR_{sed(c)} \times B_{sed} \times CF \\
 Abs_{sed-ing(a)} &= C_{sed} \times IR_{sed(a)} \times B_{sed} \times CF \\
 Risk_{sed-ing} &= \left(\frac{Abs_{sed-ing(c)} \times EF_{sed(c)} \times ED_c}{BW_c \times AT} + \frac{Abs_{sed-ing(a)} \times EF_{sed(a)} \times ED_a}{BW_a \times AT} \right) \times SF
 \end{aligned}$$

Where $Abs_{sed-ing(c)}$ and $Abs_{sed-ing(a)}$ are the absorbed doses from ingestion of sediment in mg/day in the child and the adult, respectively.



The ingestion rate of sediment was assumed to one half of the ingestion rate of soil, or 50 mg/d for adults and 100 mg/d for children.

The relative bioavailability (RBA) of arsenic in sediment was assumed to be the same as that assumed for soil (20.3%).

As with the water contact pathways, it is assumed that for adults, based on professional judgment and the assumption that residents would occasionally but infrequently contact surface water, the exposure frequency (EF) to sediment is six times/year (one day per month for six months) and for children it is 18 times/year (two days per month for six months and one day per month for six months).

Incidental Dermal Contact with Sediment

Uptake from incidental dermal contact with sediment was calculated using the following equation and assumptions:

$$\begin{aligned}
 Abs_{sed-derm(c)} &= C_{sed} \times SA_{sed(c)} \times AF_{sed} \times ABS \times CF \\
 Abs_{sed-derm(a)} &= C_{sed} \times SA_{sed(a)} \times AF_{sed} \times ABS \times CF \\
 Risk_{sed-derm} &= \left(\frac{Abs_{sed-derm(c)} \times EF_c \times ED_c}{BW_c \times AT} + \frac{Abs_{sed-derm(a)} \times SA_{sed(a)} \times EF_a \times ED_a}{BW_a \times AT} \right) \times SF
 \end{aligned}$$

Where $Abs_{sed-derm(c)}$ and $Abs_{sed-derm(a)}$ are the absorbed doses from dermal contact with sediment in mg/day in the child and the adult, respectively.

The skin surface area available for sediment contact (SA) is based on data presented in U.S. EPA's *Exposure Factors Handbook* (U.S. EPA, 2011b), and assumes contact during swimming or wading, or contact from the shore. It is based on the following:

- For adults, the value (2,960 cm²/event) assumes contact by hands, lower arms, and feet for 50% of events, and hands and lower arms for 50% of events, based on mean surface area by body part averaged for males and females.
- For children, the value (1,7500 cm²/event) assumes contact by head, hands, lower arms, feet, and lower legs for 50% of events, and hands and lower arms for 50% of events, based on mean surface area by body part averaged for children ages 2 to 6.

The sediment-to-skin adherence factor (AF) describes the mass of sediment that adheres to skin per square centimeter of skin surface. The assumed value (0.18 mg/cm²) is from U.S. EPA (2000a) and represents a reasonable upper-bound adherence factor for all exposed skin. This value is higher than that for soil because it is assumed that sediment is wet and so is more adherent.

The same dermal absorption factor (ABS) as used for the soil dermal contact pathway (0.032) was used, and is U.S. EPA's chemical-specific default for dermal contact with arsenic (U.S. EPA, 2004a).

It is assumed that for adults, the exposure frequency (EF) to sediment contact is six times/year and for children it is 18 times/year.

3.1.3 Revised Exposure Assumptions for Soil and Dust Ingestion Pathways

Relative bioavailability was recalculated using the data presented in Freeman et al. (1995) and the following equation:

$$RBA \text{ of test material} = \frac{\text{Urinary excretion fraction of arsenic in test material (soil or water)}}{\text{Urinary excretion fraction of sodium arsenate in water}}$$



Using the monkey data, which have a number of uncertainties as discussed in Section 2.2.4.2, results in RBA estimates of $20.3 \pm 3.4\%$ for soil and $29.1 \pm 0.7\%$ for dust. However, as noted in Sections 2.2.4.2 and 2.2.4.4, the bioavailability estimates from the monkey study are likely to underestimate arsenic bioavailability at the site.

In addition, the assumed relative concentration of arsenic in dust (43%) was changed based on the Pioneer Technical Services (2009) study. This study indicates that the average relative indoor dust to outdoor soil concentration ratio, combining all data for Opportunity, Anaconda West, and Anaconda East, was 130%. This value was applied in the current assessment. Particularly in Anaconda homes, concentrations in attic dust tended to be much higher than those in dust in the main living area; however, the enrichment in attic dust did not tend to be quite as high in the Opportunity, and without more data, it was assumed that contact with attic dust would be minimal. Thus, a separate assumption for exposure to attic dust was not included in this assessment. This may underestimate risks in homes where attic dust concentrations are particularly high and may be reentrained into the air, or occupants regularly spend time in the attic.

Other exposure assumptions were not changed from the CDM (1996) Baseline HHRA for the following reasons:

- **Soil ingestion rate.** The RME soil ingestion rates (100 mg/d for adults and 200 mg/d for children) were not changed as no additional site-specific data were identified that warrant an adjustment to this parameter, and these remain the U.S. EPA recommended default assumptions for this scenario (U.S. EPA, 1996b; U.S. EPA, 2012d).
- **Fraction ingested that is soil and dust.** The assumed fraction that is ingested that is soil and dust (45% soil and 55% dust) was not changed, as no additional site-specific data were identified that warrant an adjustment to this parameter, and U.S. EPA's current exposure assessment guidance (U.S. EPA, 2011b) continues to recommend this assumption.
- **Exposure duration.** The RME exposure duration values (24 years as an adult and 6 years as a child) were not changed as no additional site-specific data were identified that warrant an adjustment to this parameter and these remain the U.S. EPA recommended default assumptions for this scenario (U.S. EPA, 1996b; U.S. EPA, 2012d). However, based on site-specific information suggesting a relatively longer residence time for people who live in the Opportunity Community, these assumptions will not overestimate typical site-related risks and may underestimate risks for some members of the population.
- **Exposure frequency.** The standard RME exposure frequency value (350 d/year) was not changed as no additional site-specific data were identified that warrant an adjustment to this parameter and this remains the U.S. EPA recommended default assumptions for this scenario (U.S. EPA, 1996b; U.S. EPA, 2012d).
- **Body weight.** The RME body weight values (70 kg for an adult and 15 kg for a child) were not changed as no additional site-specific data were identified that warrant an adjustment to this parameter and these remain the U.S. EPA recommended default assumptions for this scenario (U.S. EPA, 1996b; U.S. EPA, 2012d).

3.2 Recalculation of Site-Related Risks

Site-related risks recalculated for Opportunity Community residents based on the assumptions described above are summarized in Table 8.



Table 8. Summary of Pathway-Specific Lifetime Excess Cancer Risks for Opportunity Community Residents, RME Scenario

Pathway	Cancer Risk	Percent of Total Risk
Ingestion of dust	9.0×10^{-5}	36.2%
Dermal contact with soil	1.7×10^{-6}	0.70%
Dermal contact with dust	1.0×10^{-6}	0.41%
Inhalation of soil particulate	2.5×10^{-6}	0.10%
Ingestion of produce	9.5×10^{-5}	38.4%
Ingestion of meat	4.7×10^{-5}	6.9%
Total soil-related risks	2.4×10^{-4}	98.6%
Ingestion of sediment	1.8×10^{-5}	0.73%
Dermal contact with sediment	1.2×10^{-6}	0.47%
Total sediment-related risks	3.0×10^{-6}	1.2%
Ingestion of surface or ground water	4.2×10^{-7}	0.17%
Dermal contact with surface or ground water	1.6×10^{-7}	0.01%
Total surface or ground water-related risks	4.4×10^{-7}	0.18%
TOTAL	2.5×10^{-4}	

As shown, based on the assumptions described above, four exposure pathways contribute significantly (i.e., >1%) to the total risk estimate: ingestion of soil (15.9%), ingestion of dust (36.2%), ingestion of produce (38.4%), and ingestion of meat (6.9%). All the other pathways contribute <1% to the total risk estimate but estimated risks for four other pathways (dermal contact with soil, dermal contact with dust, ingestion of sediment, and dermal contact with sediment) exceed U.S. EPA's *de minimis* lifetime excess cancer risk level of 1 in 1,000,000 (1×10^{-6}).



3.3 Recalculation of the Soil Screening Level

Overall, non-soil related pathways were estimated to contribute insignificantly to overall risk (i.e., water and sediment-related pathways were estimated to contribute <1% to the total risk). As a result, soil cleanup levels were calculated taking into account only the contribution of the soil-related pathways to total lifetime excess cancer risk from exposure to environmental arsenic. Because there is a linear relationship between soil concentration and the estimated lifetime excess cancer risk for these pathways, a soil cleanup level associated with a target cancer risk can be calculated based on the ratio of the risk estimated for the exposure pathways shown in Table 8 at the assumed soil concentration (i.e., the 95% UCL), as follows:

$$\frac{\text{Estimated risk}}{\text{Assumed soil conc (ppm)}} = \frac{\text{Target risk}}{\text{Soil screening level (ppm)}}$$

Rearranging the equation yields:

$$\text{Soil screening level (ppm)} = \frac{\text{Target risk} \times \text{Assumed soil conc (ppm)}}{\text{Estimated risk}}$$

In regard to target risk, U.S. EPA has stated that a lifetime excess cancer risk of 10^{-6} (1 in 1,000,000) is recommended as the point of departure. For example, Subpart E of the National Contingency Plan (1990) states:

EPA will set remediation goals for total risk due to carcinogens that represent an excess upperbound lifetime cancer risk to an individual to between 10^{-4} to 10^{-6} lifetime excess cancer risk. A cancer risk of 10^{-6} will serve as the point of departure for these remediation goals.

U.S. EPA's *Risk Assessment Guidance for Superfund* (RAGS) outlines the fundamental methodology for conduct of risk assessments under Superfund. RAGS Part B (U.S. EPA, 1991) provides guidance on methodologies for developing risk-based preliminary remediation goals (PRGs) and states:

For carcinogenic effects, a concentration is calculated that corresponds to a 10^{-6} incremental risk of an individual developing cancer over a lifetime as a result of exposure to the potential carcinogen from all significant exposure pathways for a given medium (Chapter 2, p. 14).

And, further:

When the cumulative current or future baseline cancer risk for a medium is within the range of 10^{-6} to 10^{-4} , a decision about whether or not to take action is a site-specific determination (Chapter 2, p. 15).

RAGS Part B further specifies

...in the absence of ARARS, the 10^{-6} cancer risk 'point of departure' is used as a starting point for analysis of remedial alternatives which reflects EPA's preference for managing risks at the more protective end of the risk range, other things being equal (Chapter 2, p. 18).

U.S. EPA (1996b) (*Soil Screening Guidance*) specifies that for calculation of soil screening levels for residential soil, the "screening level" equation corresponds to a target risk level of 10^{-6} . Overall, based on this guidance, a target risk level that does not exceed 10^{-5} (1 in 100,000) to 10^{-6} (1 in 1,000,000) is recommended.



Based on the calculated lifetime excess cancer risks for the soil pathways associated with a 95% UCL soil concentration of 184 ppm of 2.4×10^{-4} and a target cancer risk of 1.0×10^{-5} , a soil screening level of approximately 8 ppm is calculated.

$$\text{Soil screening level (mg/kgppm)} = \frac{1 \times 10^{-5} \times 184 \text{ ppm}}{2.4 \times 10^{-4}} = 7.7 \text{ ppm}$$

Thus, based on the assumptions described above, a soil cleanup level of 8 ppm is calculated associated with a lifetime excess cancer risk of 1×10^{-5} (1 in 100,000).

4.0 COMPARISON TO CLEANUP LEVELS AT OTHER SITES

Numerous states have established default soil cleanup levels for arsenic in soil, based on assumed acceptable cancer risk levels and default (non-site specific) exposure assumptions. Cleanup levels in soil for residential/unrestricted use, shown in Table 9, range from 0.039 to 40 ppm. Most of these values are based on an assumed acceptable cancer risk of 1×10^{-5} (1 in 100,000) or 1×10^{-6} (1 in 1,000,000).

Table 9. Soil Cleanup Levels for Arsenic in Soil for Residential/ Unrestricted Use for U.S. States^a

State	Cleanup Level (ppm)	Notes
CA	0.07	Cancer (10^{-6} risk level), 4% dermal absorption assumption, California Slope Factors
ME	1.4	Cancer (10^{-5} risk level), California Slope Factors
NM	3.59	Cancer (10^{-5} risk level), 33% oral bioavailability, state-specific exposure assumptions
IN	3.9	Noncancer soil-plant-human uptake (based on U.S. EPA soil screening guidance)
OH	6.7	Cancer (10^{-5} risk level), 3% dermal absorption assumption
AZ, IA, KS, KY, MA, MN, MO, MT, NE, NY, PA, RI, WA	7 to 40	State-specific natural background
TX	24	Noncancer (lower than cancer endpoint at 10^{-4} risk; 34 ppm)

^a Source: Teaf et al. (2010) and research of values set by state agencies.

The U.S. EPA Regional Screening Level (RSL) for arsenic is 0.39 ppm (U.S. EPA, 2012d), based on a lifetime excess cancer risk of 1×10^{-6} . U.S. EPA defines RSLs as follows:

They are risk-based concentrations derived from standardized equations combining exposure information assumptions with EPA toxicity data. SLs are considered by the Agency to be protective for humans (including sensitive groups) over a lifetime; however, SLs are not always applicable to a particular site and do not address non-human health endpoints, such as



ecological impacts. The SLs contained in the SL table are generic; they are calculated without site-specific information. They may be re-calculated using site-specific data.

The RSL is derived based on the following assumptions:

- Pathways: soil ingestion, inhalation of particulate, dermal contact with soil.
- Oral cancer SF = $1.5 \text{ (mg/kg BW-d)}^{-1}$
- 100% oral bioavailability (U.S. EPA default)
- 3% dermal bioavailability (U.S. EPA default for metals)
- Exposure frequency: 350 d/yr
- Exposure duration: 30 years
- Averaging time: 70 year lifetime
- Particulate emission factor (PEF) = $1.4\text{E}+09 \text{ m}^3/\text{kg}$ (EPA default)
- Soil ingestion rate: 200 mg/d for 6 years by a 15 kg child, then 100 mg/d for 24 years by 70 kg adult
- Dermal contact rate: $2800 \text{ cm}^2/\text{d}$ and absorption fraction of 0.2 mg/cm^2 for 6 years and $5700 \text{ cm}^2/\text{d}$ and absorption fraction of 0.07 mg/cm^2 for 24 years

Pathway-specific RSLs are 0.43 ppm for soil ingestion, 770 ppm for inhalation of particulate, and 4.5 ppm for dermal contact (U.S. EPA, 2012d).

Table 10 lists site-specific action levels established for arsenic in soil at other U.S. NPL sites. These sites were identified based on a review of arsenic RODs conducted by Davis et al. (2001), a summary prepared by the Agency of Toxic Substances and Disease Registry (ATSDR) on action levels presented in RODs conducted as part of a Health Consultation to evaluate the residential soil arsenic level at the Anaconda site (ATSDR, 2007), and searches of U.S. EPA's ROD database. The table also identifies the type of site (e.g., smelting, mining, wood treating, manufacturing), the basis of the action level where available, the assumed cancer risk level, and the site-specific or local background arsenic soil concentration.



Table 10. Action Levels for Arsenic in Soil at Selected U.S. Sites

Site	Type of Site Source of Contamination	Date of ROD	Site-Specific Arsenic Action Level in Soil (ppm)	Risk Level	Local Background Arsenic Soil Concentration (ppm)	Reference
Bunker Hill Site (Smelterville, ID)	Inactive mine and mill, lead and zinc smelter, and phosphoric acid fertilizer plant	1992	10 (OU3), risk based concentration and equal to background 100 (OU2), clean replacement soil must contain less than this concentration; ROD for site is based on soil lead concentration of 100	NA	10	U.S. EPA, 1992c; U.S. EPA, 2013
...



Site	Type of Site, Source of Contamination	Date of RDO	Site-Specific Arsenic Action Level in Soil (ppm)	Risk Level	Local Background Arsenic Soil Concentration (ppm)	Reference
Lava Cap Mine (Nevada County, CA)	Hardrock gold and silver mine; tailings	2004	20 (Mine Area OU), based on background	Between 10^{-4} and 10^{-6} assuming exposure through ingestion (soil, sediment, surface/ground water, dust), dermal contact, and inhalation	20	U.S. EPA, 2004b
Wingate Road Municipal Incinerator Dump (Fort Lauderdale, FL)	Municipal incinerator and landfill	1996	23 (for surface soil); (for sediment); scenario not identified	"Fall within EPA's risk range" of 1×10^{-6} to 1×10^{-4}	1.4	U.S. EPA, 1996e
RSR Corp. (Dallas, TX)	Lead smelter	1996	32.7, for worker exposure	1×10^{-5} (not based on 1×10^{-6} because that results in cleanup level below background concentrations; industrial exposure through soil ingestion and dermal contact)	NA	U.S. EPA, 1996f



Site	Type of Site/ Source of Contamination	Date of RISC	Site-Specific Arsenic Action Level in Soil (ppm)	Risk Level	Local Background Arsenic Soil Concentration (ppm)	Reference
Joseph Forest Products (Wallowa County, OR)	Wood treating using chromated copper arsenate	1992	36 for surface soils, industrial use; 336 for subsurface soils (deeper than 3 feet), for industrial use (OUI)	1×10^{-5} for industrial PRG for surface soils, approximately equal to 1×10^{-4} for residential scenario; pathways not identified	NA	U.S. EPA, 1992d

Fremont National Forest/ White King and Lucky Lass Uranium Mines (Lakeview, OR)	Mining	2001	38, recreational use (no current or likely future residential use of site)	1×10^{-6} based on recreational user scenario	6	U.S. EPA, 2001b
---	--------	------	--	--	---	-----------------

Joseph Forest Products (Wallowa County, OR)	Wood treating using chromated copper arsenate	1992	36 for surface soils, industrial use; 336 for subsurface soils (deeper than 3 feet), for industrial use (OUI)	1×10^{-5} for industrial PRG for surface soils, approximately equal to 1×10^{-4} for residential scenario; pathways not identified	NA	U.S. EPA, 1992d
---	---	------	---	--	----	-----------------

Site	Type of Site/ Source of Contamination	Date of ROD	Site-Specific Action Action Level in Soil (ppm)	Risk Level	Local Background Action Soil Concentration (ppm)	Reference
National Zinc Corp. (Bartlesville, OK)	Zinc smelting	1995	60, residential	3×10^{-5} (assumed 25% relative oral bioavailability based on Anaconda site values)	8	U.S. EPA, 1995a
Midvale Steel Corp. (Midvale, UT)	Smelting	1990	70, for residential exposure	2.6×10^{-5}	<20	U.S. EPA, 1990b
Vasquez Boulevard and I- 70 (Denver, CO)	Smelting	2003	70, residential	1×10^{-5} at background level of 15 ppm; preliminary action level was 47 ppm, level at which HQ for noncancer effects exceeds 1; based on soil and dust and garden vegetable ingestion; site-specific relative oral bioavailability estimate of 42% based on juvenile swine study	8-15	U.S. EPA, 2003a

Site	Type of Site Source of Contaminants	Date of ROD	Site-Specific Action Action Level in Soil (ppm)	Risk Level	Local Background Action Soil Concentration (ppm)	Reference
Atlantic Wood Industries (Portsmouth, VA)	Wood treating	2007 (originally 1995)	76, for worker exposure	5×10^{-6} for industrial exposure scenario (soil ingestion, dermal contact with soil, and inhalation of soil particulates by on-site workers)	"below cleanup levels for the site)	U.S. EPA, 1995d; U.S. EPA, 2007b
Whitewood Creek Mining Area (Whitewood, SD)	Gold mining and milling; tailings	1990	100, for residential exposure	1×10^{-4} ; assumes residential exposure; oral bioavailability in soil = 50%; soil ingestion pathway only	NA	U.S. EPA, 1990a



Site	Type of Site Source of Contamination	Date of ROD	Site-Specific Arsenic Action Levels in Soil (ppm)	Risk Level	Local Background Arsenic Soil Concentration (ppm)	Reference
Blackbird Mine (Lemhi County, ID)	Mining	2003	100, residential scenario (based on background)	Risk-based concentration for residential scenario = 42 ppm	100	U.S. EPA, 2003b
Davenport and Flagstaff Smelters (Sandy, UT)	Smelting	2002	126, residential	1×10^{-4} (based on direct contact, ingestion, or inhalation of soil)	NA	U.S. EPA, 2002c
Clark Fork River (Deer Lodge, MT)	Mining and smelting	2004	150, recreational	1×10^{-4} (based on ingestion and direct contact with soil)	NA	U.S. EPA, 2004c
Kennecott North Zone (Magna, UT)	Smelting	2002	200 (site is zoned manufacturing, heavy industrial, mining)	At 261 ppm, 1×10^{-5} (industrial scenario)	NA	U.S. EPA, 2002d



Site	Type of Site/ Source of Contamination	Date of RCD	Site-Specific Arsenic Action Level (ppm)	Risk Level	Local or Background Arsenic Soil Concentration (ppm)	Reference
Puget Sound Naval Shipyard (Bremerton, WA)	Shipyard Industrial waste Industrial Military installation	1997	219 (OU1) based on State of Washington Model Toxic Control Act, Method C, Industrial Cleanup Values for Soils, although current MTCA values is 20	1×10^{-6} ; Industrial (workers) only, and protection of groundwater for drinking water use	NA	U.S. EPA, 1997

Puget Sound Naval Shipyard (Bremerton, WA)	Shipyard	1997	219 (OU1) based on State of Washington Model Toxic Control Act, Method C, Industrial Cleanup Values for Soils, although current MTCA values is 20	Current MTCA value = 20 ppm for 1×10^{-6} ; based on soil ingestion only, and protection of groundwater for drinking water use	7.5	U.S. EPA, 1997
---	----------	------	--	--	-----	----------------

Silver Bow Creek/ Butte (Butte, MT)	Mining, smelting, industrial and municipal wastes	1990	250 mg/kg, residential	5.3×10^{-5} ; based on soil ingestion and dermal contact, inhalation of particulate, and dermal absorption from water; relative oral bioavailability = 18% for soil and 25% for dust	NA	U.S. EPA, 1990c
---	---	------	---------------------------	--	----	-----------------

Silver Bow Creek/ Butte (Butte, MT)	Mining, smelting, industrial and municipal wastes	1990	250 mg/kg, residential	5.3×10^{-5} ; based on soil ingestion and dermal contact, inhalation of particulate, and dermal absorption from water; relative oral bioavailability = 18% for soil and 25% for dust	NA	U.S. EPA, 1990c
---	---	------	---------------------------	--	----	-----------------



Site	Type of Site/ Source of Contamination	Date of ROD	Site-Specific Arsenic Action Level in Soil (ppm)	Risk Level	Local Background Average Soil Concentration (ppm)	Reference
Triumph Mine Tailings (Triumph, ID)	Mining tailings piles	1998	300, residential	1×10^{-4} based on soil ingestion and inhalation; "protective whether arsenic bioavailability is assumed to be 16, 28, or 60 percent" (from 1 to 5×10^{-4} depending on bioavailability)	NA	U.S. EPA, 1998d